

Federal Circuit Bar *Journal*



- ★ Artificial Intelligence Patent Infringement: Applying the *Respondeat Superior* Doctrine
- ★ “Out of This World” Litigation Has Down-to-Earth Repercussions: Blue Origin’s Bid Protest Loss and the Paradox of Applying Conventional Procedural Constraints to Unconventional Space Procurements
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Artificial Intelligence Patent Infringement: Applying the *Respondeat Superior* Doctrine

Tae Yeon (Zoe) Kim*

Introduction

Artificial Intelligence (“AI”) has great potential to solve problems in areas where human experts cannot yet make accurate predictions.¹ For example, the Food and Drug Administration (“FDA”) recently approved a WAVE surveillance model that is able to predict situations in which a patient’s vital signs will become unstable.² Trained from the electronic health records of past patients, the WAVE model triggers alerts so that rapid response nurse teams can intervene before the predicted event and stabilize the patient.³ As there are many such complex situations that human actors cannot yet accurately predict, machine learning is an important technology that enables improvements beyond our current limited understanding of the world.⁴

Even in areas where human actors can make predictions, machine learning enables automation of the predictive processes that can save businesses billions of dollars.⁵ For example, Netflix Recommendation Engine filters over 3,000 titles at a time using 1,300 recommendation clusters extracted from user preferences, thereby saving Netflix more than a billion dollars a year in

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¹ See W. Nicholson Price II & Arti K. Rai, *Clearing Opacity Through Machine Learning*, 106 IOWA L. REV. 775, 778 (2021).

² See *id.*

³ See *id.*

⁴ See *id.*

⁵ See Jacques Bughin et al., *Artificial Intelligence: The Next Digital Frontier?*, MCKINSEY GLOBAL INST. 20 (June 2017), <https://www.mckinsey.com/~media/mckinsey/industries/advanced%20electronics/our%20insights/how%20artificial%20intelligence%20can%20deliver%20real%20value%20to%20companies/mgi-artificial-intelligence-discussion-paper.ashx> [<https://perma.cc/9YY7-V5K8>].

driving its viewers' activity and avoiding cancelled subscriptions.⁶ Amazon acquired Kiwa, a robotics company using machine learning to improve the picking and packing times of packages, which lowered its operating costs by 20%, giving a return of 40% on the original investment.⁷ As more and more businesses are realizing machine learning's potential to boost financial performance, the global market for machine learning exhibited 36.1% growth from 2019 to 2020 due to higher demand in response to the COVID-19 pandemic and grew to \$15.44 billion in 2021.⁸ The market is only expected to continue to expand, with projected growth from \$21.17 billion in 2022 to \$209.91 billion in 2029 at the compound annual growth rate of 38.8%.⁹

With the expansion of the global market for machine learning and AI, courts have had to assess how this new technology fits into patent law's existing framework. To determine the patentability of AI-related inventions, U.S. federal courts and the United States Patent and Trademark Office ("USPTO") have adopted the Supreme Court's two-part test for software patentability from *Alice Corp. v. CLS Bank International*.¹⁰ Although AI is a relatively new technology, cases analyzing its patentability have been fairly extensive,¹¹ and

⁶ See Rachel Meltzer, *How Netflix Utilizes Data Science*, LIGHTHOUSE LABS (June 17, 2022), <https://www.lighthouselabs.ca/en/blog/how-netflix-uses-data-to-optimize-their-product> [https://perma.cc/MR7B-C3J7].

⁷ See Eugene Kim, *Amazon's \$775 Million Deal for Robotics Company Kiva Is Starting to Look Really Smart*, BUS. INSIDER (June 15, 2016), <https://finance.yahoo.com/news/amazons-775-million-deal-robotics-200246489.html> [https://perma.cc/Y82W-ZMBW]; Bughin, *supra* note 5, at 20.

⁸ See *Machine Learning Market Size, Share & COVID-19 Impact Analysis*, FORTUNE BUS. INSIGHTS (Mar. 2022), <https://www.fortunebusinessinsights.com/machine-learning-market-102226> [https://perma.cc/J3QC-DAL2].

⁹ See *id.*

¹⁰ 573 U.S. 208, 217–18 (2014); see Ryan N. Phelan, *How the Courts Treat Artificial Intelligence (AI) Patent Inventions: Through the Years Since Alice*, MARSHALL GERSTEIN PATENTNEXT (Mar. 12, 2021), https://www.patentnext.com/2021/03/how-the-courts-treat-artificial-intelligence-ai-patent-inventions-through-the-years-since-alice/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=LinkedIn-integration [https://perma.cc/6APQ-HYFD] (summarizing the *Alice* two-part test: under *Alice* step 1, courts ask whether the AI invention “directs to” an “abstract idea” of “mental processes” or “mathematical concepts,” for which if the AI invention does not, then it is patentable; if an abstract idea is found, under *Alice* step 2, courts ask whether the AI invention possesses “inventive concept” that amounts to “significantly more” than the abstract idea itself, for which if the AI invention does, then it is patentable, but if it does not, then it is not patentable).

¹¹ See, e.g., *I/P Engine, Inc. v. AOL Inc.*, 576 Fed. App'x 982, 994–95, 995 n.4 (Fed. Cir. 2014) (Mayer, J., concurring) (per curiam) (stating that where claims described a system for filtering “information for relevance to a user's query using combined content and collaborative data,” but lacked as an element the use of a “complex neural network function” that the

the USPTO has even released guidance that provides examples of patent-eligible AI inventions.¹²

For the issue of AI patent infringement, however, it is still unclear which entities, if any, can be held liable when AI infringes a patent. Although a claim of patent infringement by an AI invention has been brought, it was dismissed without reaching the merits of the infringement question due to initial findings of patent invalidity.¹³ Software and AI are typically patented as method claims because their algorithms are the methods, or the steps, of providing a service, rather than a physical apparatus that actually performs the service.¹⁴

patentee argued enabled the collaboration, the claimed invention is not patentable); *Vehicle Intel. & Safety LLC v. Mercedes-Benz USA, LLC*, 78 F. Supp. 3d 884, 893 (N.D. Ill. 2015) (holding that “expert system” used to screen operators for impairments and control the equipment if operator’s impairment is detected is not patentable because it is directed to “abstract ideas” as its method could be “performed entirely in the human mind”); *Purepredictive, Inc. v. H2O AI, Inc.*, No. 17-cv-03049, 2017 WL 3721480, at *1, *8, *10–12 (N.D. Cal. Aug. 29, 2017) (holding that “an automated factory for predictive analytics” claimed is not patentable as directed to “a mental process” by merely using “mathematical algorithms to perform predictive analytics” and lacking “inventive concept” because it referenced generic “modules” and failed to describe “specific system architecture”); *Power Analytics Corp. v. Operation Tech., Inc.*, No. SA-CV16-01955, 2017 WL 5468179, at *4–6 (C.D. Cal. July 13, 2017) (holding that a “machine learning engine” claimed is not patentable for being abstract and lacking “inventive concept” because it merely described the invention in functional terms without adding any specific inventive implementation); *Applied Predictive Techs., Inc. v. Marketdial, Inc.*, No. 2:19-cv-00496, 2020 U.S. Dist. LEXIS 221981, at *23 (D. Utah Nov. 25, 2020) (holding that claims are not patentable because they lacked AI-specific elements and were rather “directed to the abstract concept of optimizing parameter settings for business initiative tests”).

¹² See *Subject Matter Eligibility Examples: Abstract Ideas*, USPTO 1, 8–9 (Jan. 7, 2019), https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf [<https://perma.cc/A6GR-NPFH>] (examples to be used in conjunction with the 2019 Revised Patent Subject Matter Eligibility Guidance and “intended to be illustrative of the claim analysis” under that Guidance).

¹³ See *PurePredictive*, 2017 WL 3721480, at *1–2, *7 (wherein plaintiff PurePredictive with patent for “an automated factory for predictive analytics,” using AI’s predictive modeling to provide insight into business data, claimed direct and indirect infringement from H2O, providing machine learning platform called “H2O with AutoML” integrated with applications and data products, but the claim was dismissed on Rule 12(b)(6) motion due to the holding that PurePredictive’s claims are unpatentable as they are directed to abstract ideas and lack inventive concept), *aff’d*, 741 F. App’x 802 (Fed. Cir. 2018).

¹⁴ See *Ameya V. Paradkar & Ji Young Park, Infringement Issues in Artificial Intelligence Patents*, L. INTELLIGENCER (Mar. 29, 2019), <https://www.blankrome.com/publications/infringement-issues-artificial-intelligence-patents> [<https://perma.cc/H47P-VPKL>]; Timothy R. Holbrook, *Method Patent Exceptionalism*, 102 IOWA L. REV 1001, 1032 (2016).

However, the available causes of action under 35 U.S.C. § 271,¹⁵ the patent infringement statute, fail to assign liability to manufacturers when their AI infringes the method patents of other AI inventions and software.¹⁶ This is also the case when injured patent owners try to hold infringers liable under the *respondeat superior* doctrine, which equates employee action to corporate action and has not been extended to hold manufacturers liable for infringement by their AI inventions.¹⁷

This Note argues that the Federal Circuit should extend the *respondeat superior* doctrine to equate algorithmic action to corporate action when AI infringes a patent because current alternatives fail to hold AI manufacturers liable and thereby do not deter manufacturers from producing and profiting from AI inventions that infringe others' patents. By assigning AI liability to corporations through corporate law, manufacturing entities, the ones that produce and profit from the AI, can be held accountable for patent infringement committed by their AI inventions. Part I of this Note describes developments in AI technology, such as machine learning, the causes of action under the patent infringement statute, and basic principles of corporate law, specifically the *respondeat superior* doctrine and products liability. Part II applies 35 U.S.C. § 271 and the *respondeat superior* doctrine to acts of patent infringement by AI inventions and concludes that current theories of direct, divided, and indirect infringement fail to hold all responsible manufacturers liable for infringement by their AI inventions and the current application of the *respondeat superior* doctrine is insufficient in filling that gap. Finally, Part III of this Note recommends that the Federal Circuit extend the *respondeat superior* doctrine to equate algorithmic action to corporate action, in addition to equating employee action to corporate action, in order to properly assign liability to all responsible manufacturers when their AI infringes a patent.

I. Background: AI and the Applicable Law

A. Artificial Intelligence

AI is the use of computer programs or machine processes to imitate intelligent human behavior.¹⁸ This imitation may include thinking like humans by employing “cognitive architectures [or] neural networks,” or acting like humans by operating “natural language processing, knowledge representation,

¹⁵ 35 U.S.C. § 271 (2018).

¹⁶ See discussion *infra* Section III.A.

¹⁷ See discussion *infra* Section III.B.

¹⁸ See Sean Semmler & Zeeve Rose, Note, *Artificial Intelligence: Application Today and Implications Tomorrow*, 16 DUKE L. & TECH. REV. 85, 86 (2017).

automated reasoning, [or] learning.”¹⁹ AI may “think rationally” through “logic solv[ing], inference, [or] optimization,” and “act rationally” by “achiev[ing] goals via perception, planning, reasoning, learning, communicating, decision-making, and acting.”²⁰

Machine learning is a subset of artificial intelligence that does not rely on rule-based programming, but rather automatically improves upon its algorithms from patterns detected in accumulated data to accomplish complex tasks or make predictions.²¹ In theory, the process is quite simple: the system merely needs to be trained with enough predetermined data until it can arrive at its own valuations and judgements on new data based on accumulated data from similar tasks.²² For example, a learning algorithm may sort through 100,000 X-rays of human lungs, 5,000 of which have been labeled by radiologists as containing cancerous tumors, adjust its algorithm according to common patterns in the X-rays containing cancerous tumors, and determine whether a newly entered X-ray contains a cancerous tumor.²³

In practice, however, the machine learning process is much more complex.²⁴ It requires at least seven steps: a manufacturer must (1) gather data that is large enough to enable robust predictive power; (2) prepare data by selecting the input features, classifying the output labels, and randomizing the set; (3) choose a learning algorithm that is suitable for the type of data, such as one specifically for image data, text data, or numeric data; (4) train the algorithm through a series of iterations that adjust the model parameters for translating inputs into outputs; (5) evaluate the algorithm by testing it with data that has not been entered in training; (6) tune the algorithm by testing the parameters implicitly assumed during training; and (8) test the algorithm by applying data from an entirely new source to validate its predictive power.²⁵ This multi-step method is why, in a common life cycle for machine learning technology, multiple manufacturing entities are involved: the technology is often developed by one entity, sold to and owned by a second entity, trained by a third entity, and operated by a fourth entity.²⁶

¹⁹ Artificial Intelligence Job Opportunities and Background Summary Act of 2018, H.R. 4829, 115th Cong. § 4(1) (2018).

²⁰ *Id.*

²¹ See Harry Surden, *Machine Learning and Law*, 89 WASH. L. REV. 87, 88–89 (2014).

²² See Price & Rai, *supra* note 1, at 777–78.

²³ See *id.*

²⁴ See Yufeng G, *The 7 Steps of Machine Learning*, TOWARDS DATA SCI. (Aug. 31, 2017), <https://towardsdatascience.com/the-7-steps-of-machine-learning-2877d7e5548e> [<https://perma.cc/RR8G-PYWA>].

²⁵ See *id.*

²⁶ See Jacqueline K. S. Lee et al., *Catch Me If You Can: Litigating Artificial Intelligence Patents*, JONES DAY: INSIGHTS (Dec. 2017), <https://www.jonesday.com/en/insights/2017/12/>

B. Direct Infringement: 35 U.S.C. § 271(a)

Section 271(a) defines direct infringement as occurring when “whoever without authority makes, uses, offers to sell, or sells any patented invention.”²⁷ However, the law treats method claims differently from other types of claims like machine, manufacture, or composition of matter claims.²⁸ Because a method claim protects the steps in a process, rather than the apparatus that performs the steps, method claims generally cannot be infringed by making, selling, or offering to sell.²⁹ Even when a party makes or sells an apparatus capable of performing a claimed method, infringement cannot be found because the method claim protects only the method itself and not the unclaimed practicing apparatus.³⁰ Furthermore, a sale requires “a thing capable of being transferred,” but a party’s performance of the steps of a method claim in exchange for payment is intangible and, consequently, is not property that is capable of being transferred.³¹ In applying such reasoning to software, the Federal Circuit concluded that software has the potential to perform a claimed method but is not the method itself, since it “is not itself a sequence of actions, but rather . . . a set of instructions that directs hardware to perform a sequence of actions.”³² Therefore, “a party that sells or offers to sell software containing instructions to perform a patented method does not infringe the [method] patent under § 271(a).”³³

For the use of a method patent to constitute direct infringement, all the steps of a method claim must be performed by a single entity.³⁴ While the

catch-me-if-you-can-litigating-artificial-intelligence-patents [<https://perma.cc/BCX2-KPBH>].

²⁷ 35 U.S.C. § 271(a) (2018). Under § 271(a), direct infringement also occurs when “whoever without authority . . . imports into the United States any patented invention during the term of the patent.” *Id.* This kind of direct infringement is not the subject of this Note.

²⁸ See Holbrook, *supra* note 14, at 1010.

²⁹ See *id.*

³⁰ See *Standard Havens Prods. v. Gencor Indus.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991) (“The ‘938 patent claims a method for producing asphalt, not the apparatus for implementing that process. Thus, the sale in the United States of an unclaimed apparatus alone does not make Gencor a contributory infringer of the patented method.”); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993) (explaining *Standard Havens* as “the method claims of the patent at issue were held not directly infringed by the mere sale of an apparatus capable of performing the claimed process.”).

³¹ *NTP, Inc. v. Rsch. In Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005) (holding that RIM’s performance of some steps of the asserted method claims as service to its customers are not infringing sales or offers to sell the claimed method).

³² *Ricoh Co. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1335 (Fed. Cir. 2008).

³³ *Id.*

³⁴ See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam) (“Direct infringement under § 271(a) occurs where all steps

patent infringement statute does not define “use,” it has been interpreted broadly by courts to mean “to put into service any given invention.”³⁵ For apparatus or system claims, for which infringement may be found by the use of an infringing machine or the control of an infringing network, the act of infringement does not necessarily have to be conducted by a single party, nor by the use or control of every component, as long as that party “control[s] the system as a whole and obtain[s] benefit from it.”³⁶

For method claims, however, courts have not only concluded that every step of the claimed method must be carried out, but also that every step must be done by a single entity.³⁷ Reasoning that method claims are intangible and harder to trace to an exact controlling party or step within a series, courts established a higher threshold for proving direct infringement of method claims, requiring the infringer to itself perform all the steps of a claimed method to be held liable.³⁸ For example, in *International Business Machines Corp. v. Booking Holdings Inc.*,³⁹ the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) held that the alleged infringer’s application did not infringe the method claim for presenting advertising so that the application and the advertisement are concurrently displayed because the alleged infringer did not perform one of the three steps in the claimed method.⁴⁰ Although the manufacturer performed two of the three steps by structuring the application so it was presented at the first portion of display and structuring the advertisements so they were presented at the second portion of display, the third step of storing the advertising objects at the reception system occurred on application users’ web or mobile devices, so the court held that the manufacturer was not liable for infringement of the method patent.⁴¹

of a claimed method are performed by or attributable to a single entity.”).

³⁵ *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10–11 (1913); *see NTP*, 418 F.3d at 1316–17.

³⁶ *Centillion Data Sys. v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279, 1284 (Fed. Cir. 2011).

³⁷ *See Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976).

³⁸ *See id.*; Mark A. Lemley et al., *Divided Infringement Claims*, 33 AIPLA Q.J. 255, 275 (2005) (explaining that direct infringement remedies are more readily available for apparatus claims because “some act of making, using, selling, or importing will eventually correspond to the claimed apparatus, even if based originally on contributions from multiple parties”).

³⁹ 775 Fed. App'x 674 (Fed. Cir. 2019).

⁴⁰ *See id.* at 679–80.

⁴¹ *See id.*

C. Divided Infringement: *Akamai*

Akamai Technologies, Inc. v. Limelight Networks, Inc.'s⁴² theory of divided infringement presents an exception to the general rule that all steps of a method must be performed by a single entity for a finding of direct infringement.⁴³ In *Akamai*, the Federal Circuit found that Limelight, a provider of internet services, infringed a method claim for delivering content over the internet even though the provider's customers performed one of the steps of the method claim.⁴⁴ In doing so, the court articulated the test for divided infringement: when more than one actor is involved in practicing method steps, a single entity may be held liable for another's performance of the steps where (1) "that entity directs or controls others' performance" or (2) "the actors form a joint enterprise."⁴⁵

The analysis for determining whether third party actions are attributable to a single entity is conducted through the general tort concept of vicarious liability, which assigns liability to a supervisory party for the conduct of a subordinate or associate based on the privity between the two parties.⁴⁶ The requisite direction or control may be found when a manufacturer conditions the customers' performance of a method step by a legal obligation or when a manufacturer interposes that step as an unavoidable technological prerequisite to participation.⁴⁷ In *Akamai*, even though Limelight's customers performed the content tagging step of Akamai's method, the Federal Circuit held that Limelight was liable for infringement because it conditioned the use of its network to the customers' performance of content tagging and thus directed or controlled the customers' infringing act.⁴⁸

D. Indirect Infringement: Inducement 35 U.S.C. § 271(b) and Contributory Infringement 35 U.S.C. § 271(c)

Unlike direct infringement, the two forms of indirect infringement, inducement and contributory infringement, require the alleged infringer to have the mental state of intent or knowledge for a finding of infringement.⁴⁹ Inducement requires proof of (1) direct infringement, (2) specific intent to

⁴² 797 F.3d 1020 (Fed. Cir. 2015) (en banc) (per curiam).

⁴³ See *id.* at 1022.

⁴⁴ See *id.* at 1025.

⁴⁵ *Id.* at 1022.

⁴⁶ See *id.* at 1022–23.

⁴⁷ See *id.* at 1024–25.

⁴⁸ See *id.*

⁴⁹ See *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488, 491 (1964).

induce a third party to infringe, and (3) an affirmative act by the inducer.⁵⁰ Although § 271(b) does not expressly refer to the inducer's knowledge of the infringed patent, courts have required patent owners to prove the intent element by showing the inducer's actual knowledge or willful blindness.⁵¹ Contributory infringement requires proof that a component was used (1) in direct infringement without any substantial non-infringing uses and (2) with knowledge that the component was especially adapted for the infringing use.⁵² Mere knowledge of possible infringement or the selling of a product suitable for some lawful use that infringes a patent after the sale is not sufficient to satisfy the knowledge or intent requirement.⁵³ For example, in *Vita-Mix Corp. v. Basic Holding, Inc.*,⁵⁴ the alleged infringer's knowledge that the blender's blades could be positioned in a vertical position to infringe the patent was not sufficient to show the alleged infringer intended for, or knew of, the infringement because the blender could also be used in a sideways position.⁵⁵

Furthermore, contributory infringement requires that the instrument used for direct infringement qualify as a "component" under § 271(c), which is a material or apparatus for use in practicing a patented process that constitutes a material part of the invention.⁵⁶ While courts have repeatedly interpreted mechanical devices as components with the capacity to enable infringement of method patents,⁵⁷ the law is still unclear as to whether abstract software servers are within the scope of components covered in § 271(c). In *Microsoft Corp. v. AT & T Corp.*,⁵⁸ AT & T sued Microsoft alleging that Microsoft's operating system, which contained a software code that enabled a computer to process speech upon installation, infringed AT & T's patent for an apparatus that digitally encodes and compresses recorded speech.⁵⁹ The Supreme

⁵⁰ See *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930, 936–37 (2005); *DSU Med. Corp.*, 471 F.3d at 1306.

⁵¹ See *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765, 769 (2011) (explaining the two basic requirements for establishing willful blindness: "(1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.").

⁵² See *C.R. Bard, Inc. v. Advanced Cardiovascular Sys.*, 911 F.2d 670, 675 (Fed. Cir. 1990).

⁵³ See *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009); *DSU Med. Corp.*, 471 F.3d at 1305.

⁵⁴ 581 F.3d 1317 (Fed. Cir. 2009).

⁵⁵ See *id.* at 1328.

⁵⁶ See 35 U.S.C. § 271(c) (2018).

⁵⁷ See, e.g., *T.D. Williamson, Inc. v. Laymon*, 723 F. Supp. 587 (N.D. Okla. 1989); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.* No. 95 CIV 8833, 2001 WL 1263299 (S.D.N.Y. Oct. 19, 2001).

⁵⁸ 550 U.S. 437 (2007).

⁵⁹ See *id.* at 446.

Court interpreted “component” in § 271(f) to only include physical copies of software.⁶⁰ Accordingly, the Court held that Microsoft did not infringe because it sent the computer software to its foreign recipients through a master disk to be copied abroad, and therefore, the copies, or the “components,” were not supplied from the United States by Microsoft.⁶¹

E. Respondeat Superior Doctrine

Under corporate law, corporations are recognized as legal entities that can be held liable in all statutes that assign civil or criminal liability to people.⁶² In equating corporations to people, a corporation is comprised of a “body corporate,” the fictional body through which the corporation acts, and a “corporate mind,” the fictional mind through which the corporation thinks.⁶³ These parts are defined by the law through the agency doctrine of *respondeat superior*, Latin for “let the master answer.”⁶⁴ The *respondeat superior* doctrine equates the employees’ bodies to the “body corporate” and the employees’ minds to the “corporate mind,” thereby holding corporations liable for their employees’ actions, thoughts, and torts.⁶⁵

The *respondeat superior* doctrine, however, only holds corporations liable for their employees’ actions when corporations have control over, and receive benefits from, the employees’ actions.⁶⁶ In other words, application of the doctrine requires that employees act within the scope of their employment and intend to benefit their employer through their conduct.⁶⁷ Employees act within their scope of employment when they perform work assigned by their employer or engage in a course of conduct subject to their employer’s control.⁶⁸ When employees act without any intention to serve the purpose of their employer, and only act in furtherance of themselves, their actions are

⁶⁰ See *id.* at 452–54.

⁶¹ See *id.*

⁶² See 1 U.S.C. § 1 (2018) (“In determining the meaning of any Act of Congress, unless the context indicates otherwise . . . the words ‘person’ and ‘whoever’ include corporations . . . as well as individuals”).

⁶³ See Mihailis E. Diamantis, *Algorithms Acting Badly: A Solution from Corporate Law*, 89 GEO. WASH. L. REV 801, 814 (2021).

⁶⁴ See *e.g.*, *Hall v. Mastec N. Am., Inc.*, No. EDCV 14-02048, 2015 WL 13917178, at *2 (C.D. Cal. Mar. 10, 2015).

⁶⁵ See *Old Monastery Co. v. United States*, 147 F.2d 905, 908 (4th Cir. 1945).

⁶⁶ See *United States v. Hilton Hotels Corp.*, 467 F.2d 1000, 1004, 1006 n.4 (9th Cir. 1972).

⁶⁷ See *id.* at 1004.

⁶⁸ See *United States v. Automated Med. Lab’ys, Inc.*, 770 F.2d 399, 407 (4th Cir. 1985).

not representative of the corporate employer's actions, and thus the *respondeat superior* doctrine will not apply.⁶⁹

By holding employers liable for their employees' torts, the *respondeat superior* doctrine has been successful in incentivizing corporations to practice more care in preventing injuries to their customers by taking additional precautions and investing more resources into training, monitoring, and disciplining their employees.⁷⁰ Similarly, economic arguments praise the *respondeat superior* doctrine for assigning liability to the "least-cost avoider," as corporations are in the best position to control the actions of their employees and can most efficiently prevent their losses by adjusting their level of precautions to the most efficient point in conducting their business.⁷¹

Under the current application of the *respondeat superior* doctrine, corporations can only act through natural persons,⁷² so in order for corporations to be held liable for the algorithms of their AI, their algorithmic behavior must be traced back to human behavior and be supported by human agency.⁷³ If a manufacturing entity's employee purposely designs AI to engage in illegal behavior by writing its code, compiling its data, and training its inputs and outputs to achieve exactly that illegal behavior, the manufacturing entity can be held liable for the AI's actions.⁷⁴ In a successful antitrust investigation, criminal charges for price colluding by algorithmic behavior were filed against corporations that sold posters through Amazon Marketplace, which operates as an auction model.⁷⁵ The algorithms of co-conspiring retailers were coordinated to match prices; one retailer's algorithm was programmed to search for the lowest price of a product sold by a non-conspiring retailer and to set its price just below that of the non-conspiring retailer's, while another retailer's algorithm was programmed to match that co-conspiring retailer's lowered

⁶⁹ See *id.*

⁷⁰ See Brent Fisse, *Reconstructing Corporate Criminal Law: Deterrence, Retribution, Fault, and Sanctions*, 56 S. CAL. L. REV. 1141, 1192–97 (1983).

⁷¹ See Robert A. Prentice, *Conceiving the Inconceivable and Judicially Implementing the Preposterous: The Premature Demise of Respondeat Superior Liability Under Section 10(b)*, 58 OHIO ST. L.J. 1325, 1386 (1997).

⁷² See *In re C.W. Mining Co.*, 636 F.3d 1257, 1266 (10th Cir. 2011).

⁷³ See *Diamantis*, *supra* note 63, at 816 (arguing that *respondeat superior* doctrine is not broad enough because modern corporations act through their algorithms, so the failure to recognize algorithmic actions as corporate actions leaves a doctrinal gap in assigning liability to corporations).

⁷⁴ See Andrew C. Finch, Acting Assistant Att'y Gen., Dep't of Just., Antitrust Div., Remarks at the 44th Annual Conference on International Antitrust Law and Policy (Sept. 14, 2017), <https://www.justice.gov/opa/speech/file/996756/download> [<https://perma.cc/329T-U9KN>].

⁷⁵ See Plea Agreement at 4, *United States v. Topkins*, No. CR 15-00201 (N.D. Cal. 2015) (pleading guilty to violating Sherman Act § 1 and agreeing to pay a \$20,000 criminal fine).

price.⁷⁶ Although the price-colluding action was carried out by algorithms, the commands in these pricing algorithms were piecewise and constant, so the Department of Justice (“DOJ”) was able to equate them to automated employee action and press charges against the conspiring corporations.⁷⁷

F. Products Liability

Another mechanism through which corporate law assigns liability to corporations is through products liability.⁷⁸ Similar to the rationale for the *respondeat superior* doctrine, products liability imposes liability on corporations because they are the “least-cost avoiders” in taking affirmative steps to prevent injuries by being best-situated to assess losses and allocate resources to preventative efforts.⁷⁹ However, products liability goes a step further and holds corporations strictly liable for their products’ manufacturing or design defects regardless of employee fault, since requiring tort claimants to pinpoint an exact error in the manufacturing or design process that is attributable to an employee’s fault creates a prohibitive evidentiary barrier to potential recovery.⁸⁰

II. Analysis: The Law Applied to Patent Infringement by AI

A. Current Causes of Action Under the Patent Infringement Statute Fail to Hold Manufacturing Entities Liable for Patent Infringement by AI Systems

1. Direct Infringement: 35 U.S.C. § 271(a)

Although the Federal Circuit has not given a definite answer on whether method claims can be infringed by making, selling, or offering to sell,⁸¹ its reasoning for excluding software from such infringement squarely applies to AI. AI is most often provided to customers through software as a service model, where a provider or an operator hosts the software, neural network, or machine learning algorithm on its servers and permits customers to access

⁷⁶ See *id.* at 3–4.

⁷⁷ See *id.*

⁷⁸ See *E. River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858, 866 (1986).

⁷⁹ See Saul Levmore, *Obligation or Restitution for Best Efforts*, 67 S. CAL. L. REV. 1411, 1416–17 (1994); see also *Escola v. Coca Cola Bottling Co. of Fresno*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring).

⁸⁰ See Diamantis, *supra* note 63, at 823.

⁸¹ See *Ricoh Co. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1335 (Fed. Cir. 2008) (“As did the court in *NTP*, we conclude that we need not definitively answer this question to conclude as a matter of law that Quanta did not sell or offer to sell the invention covered by Ricoh’s method claims.”).

the server through a subscription.⁸² Similar to software which has the potential to perform a claimed method but is not the method itself,⁸³ it is arguable that AI software, neural networks, machine learning algorithms, or their servers are not the performance of a method, but rather the instructions and instrumentality of a method that merely present a potential to perform a claimed method and cannot be made, sold, or offered for sale in violation of § 271(a). Therefore, the only potential cause of action for patent infringement under § 271(a) is the use of AI.

However, for a method claim, the infringing use generally requires that all the steps of the method be performed by a single entity.⁸⁴ For AI that is hosted on a producer's or operator's server, the input data that is required for the software, neural network, or algorithm to perform and generate an output must be provided by the end user.⁸⁵ Furthermore, complex AI such as machine learning is the coordinated effort of multiple entities in charge of separate tasks like gathering data, preparing data, developing an algorithm, training the algorithm, tuning the algorithm, and testing the algorithm.⁸⁶ While it is possible for an end user to perform all the steps of a method by inputting data and receiving an output from AI,⁸⁷ the entities that manufacture AI are likely only performing some of the steps of the method⁸⁸ and thus cannot be held liable under traditional direct infringement.⁸⁹ Like *International Business Machines*, in which the court did not find direct infringement because the alleged infringer did not perform the storing step of the claimed method that occurred on the users' devices,⁹⁰ direct infringement cannot be found for AI manufacturing entities because the input step of the AI system occurs from the end users' actions and devices, not by the manufacturing entities'.⁹¹ As a result, AI manufacturers cannot be held liable under direct infringement because no single manufacturing entity performs all the steps of a claimed software or AI method.

⁸² See Paradkar & Park, *supra* note 14.

⁸³ See *Ricoh Co.*, 550 F.3d at 1335.

⁸⁴ See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (per curiam).

⁸⁵ See Paradkar & Park, *supra* note 14.

⁸⁶ See Yufeng G, *supra* note 24.

⁸⁷ See *id.*; Paradkar & Park, *supra* note 14.

⁸⁸ See *supra* notes 24–25 and accompanying text.

⁸⁹ See *Akamai*, 797 F.3d at 1022; *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976); *Int'l Bus. Machs. Co. v. Booking Holdings Inc.*, 775 Fed. App'x 674, 679 (Fed. Cir. 2019).

⁹⁰ See *Int'l Bus. Machs. Corp.*, 775 Fed. App'x at 679.

⁹¹ Cf. *id.* (finding that the alleged infringer was not liable for direct infringement because the entity did not itself perform all the steps of the method claim).

2. *Divided Infringement: Akamai*

Akamai assigns liability to manufacturers when customers' infringing performance of method steps is a legal obligation or an unavoidable technological prerequisite, such that the manufacturer has directed or controlled the customers' performance and may be held liable for the customers' infringement.⁹² Because of this, even though end users of AI may infringe a method step by providing the input data, the users may not be liable for the infringing act if the input is an unavoidable technological prerequisite to obtaining an output from AI.⁹³ However, complex AI such as machine learning systems are often the product of multiple manufacturing entities that oversee separate tasks, such as developing the learning algorithm, gathering and preparing training data, training the algorithm through iterations, testing and tuning the system, or operating the system.⁹⁴ While each of these manufacturing entities contributes to the resulting infringing AI in one way or another, only the operator of the AI interacts with end users by providing the subscription and instructions for the use of the AI server.⁹⁵ Accordingly, all the other manufacturing entities that coded the learning algorithm, prepared the training data, or trained the AI cannot be held liable under divided infringement despite their involvement in its development, as they lack the requisite interactions with the end users that may amount to directing or controlling end users' performance.⁹⁶

As an operating entity would provide the subscription and instructions for the use of the AI server to the end users,⁹⁷ the operating entity's actions may be argued as directing or controlling end users' performance. Like *Akamai*, in which the provider of the internet services was found liable for divided infringement because it conditioned the use of its network to the customers' performance of a step,⁹⁸ an AI operating entity may be found liable for divided infringement because it conditions AI's output on the end users' performance of the input step. However, divided infringement is derived from the general tort concept of vicarious liability, and "an actor infringe[s] vicariously by profiting from direct infringement if that actor has the right and ability to stop or limit the infringement."⁹⁹ For a complex AI such as a machine learn-

⁹² See *Akamai*, 797 F.3d at 1022.

⁹³ Cf. *id.*

⁹⁴ See Lee et al., *supra* note 26.

⁹⁵ See Paradkar & Park, *supra* note 14.

⁹⁶ See *id.*

⁹⁷ See *id.*

⁹⁸ See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc).

⁹⁹ Christopher J. White & Hamid R. Piroozi, *Drafting Patent Applications Covering Artificial Intelligence Systems*, LANDSLIDE, Jan./Feb. 2019, at 12, 16.

ing system, arguably, none of the manufacturing entities have the ability to contain the infringement because a machine learning system automatically improves upon its algorithms by its accumulated data.¹⁰⁰ As a result, even an operating entity may not be held liable for AI's patent infringement because it lacks the requisite control for vicarious liability.

Although numerous manufacturing entities all contribute to the programming and training of AI, ultimately, it is the AI itself that changes its algorithms to infringe upon a method claim.¹⁰¹ AI may even infringe a method claim only after the initial sale, as the algorithms continue to change by customers' use and the integration of the customers' data.¹⁰² Because of this, even for an operating entity that provides the instructions and subscriptions for the use of AI, the requisite control for vicarious liability may not be found since it is the AI itself that develops the algorithms that infringe a patent. As such, divided infringement creates a very tenuous position for patent owners: they must convince the court to accept the oversimplified explanation that an operator is vicariously liable for providing the instructions and not turning off the server and to ignore the machine learning system's ability to automatically improve and the fault attributable to numerous other manufacturing entities that are also responsible for the AI.

3. Indirect Infringement: Inducement 35 U.S.C. § 271(b) and Contributory Infringement 35 U.S.C. § 271(c)

Indirect infringement's requisite elements of intent and knowledge are also difficult to establish for AI manufacturers because they are contrary to the very nature of machine learning training and operation. Because a machine learning system is designed with the very purpose of arriving at its own codes, rather than having a human write every line of code, anticipate all inputs, and specify all outputs, the notion that an alleged infringer would have predicted the algorithmic outcome of a machine learning system to infringe a patent is in conflict with the basic principles of how the technology operates.¹⁰³ Furthermore, as the machine learning system arrives at its own codes through autonomous improvements, the resulting algorithm is often inscrutable and so complicated that no human could have designed it

¹⁰⁰ See Surden, *supra* note 21, at 89; INFO. COMM'RS OFF., BIG DATA, ARTIFICIAL INTELLIGENCE, MACHINE LEARNING AND DATA PROTECTION 7 (2017), <http://www.ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf>.

¹⁰¹ See Surden, *supra* note 21, at 93, 97.

¹⁰² See Paradkar & Park, *supra* note 14.

¹⁰³ See Matthew Carroll, *The Complexities of Governing Machine Learning*, DATANAMI (Apr. 27, 2017), <https://www.datanami.com/2017/04/27/complexities-governing-machine-learning/> [https://perma.cc/GF9C-67RY].

from the ground up nor track the code backwards.¹⁰⁴ This, in turn, renders it impossible for a patent owner to identify the exact points that could evidence a manufacturing entity's infringing intent or knowledge amongst the transmitted data flow and changes in the code.¹⁰⁵

Even if a patent owner is able to pinpoint the exact code that demonstrates the infringer's intent or knowledge, these elements cannot be met because mere knowledge of capability of infringement is insufficient to satisfy the intent and knowledge elements; specific knowledge of infringement is required.¹⁰⁶ For inducement, a patent owner would not be able to prove that a manufacturing entity knowingly induced infringement because even though every manufacturing entity may have contributed to the machine learning system, none of them could have predicted the resulting infringing algorithm because it is the machine learning system that automatically learns from new data and changes its own algorithm in an infringing manner.¹⁰⁷

Similarly, for contributory infringement, a patent owner cannot prove that a manufacturing entity knew that its machine learning server was especially adapted for an infringing use because manufacturing entities cannot predict the changes that a machine learning system undergoes through its training and operation.¹⁰⁸ Like *Vita-Mix*, in which the alleged infringer's mere knowledge of the possibility that the blender could infringe the patent if positioned in a certain vertical position was found insufficient to prove intent or knowledge,¹⁰⁹ AI manufacturers' mere knowledge that it is possible for AI to eventually infringe a patent is insufficient to prove intent or knowledge.¹¹⁰ Manufacturers must have specific intent or knowledge to be held liable for indirect infringement; this is impossible because the machine learning system's self-learning ability contradicts such ability to predict the exact infringement.¹¹¹ As a result, both inducement and contributory infringement fail to hold AI manufacturers liable for patent infringement.

In addition to the difficulty of proving manufacturing entities' intent and knowledge, inducement would not be a viable cause of action for patent owners to establish infringement because inducement requires an affirmative

¹⁰⁴ See Andrew D. Selbst & Solon Barocas, *The Intuitive Appeal of Explainable Machines*, 87 FORDHAM L. REV. 1085, 1089–90 (2018).

¹⁰⁵ See *id.* at 1094.

¹⁰⁶ See *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009); *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305–06 (Fed. Cir. 2006) (en banc).

¹⁰⁷ See *Paradkar & Park*, *supra* note 14.

¹⁰⁸ See *id.*

¹⁰⁹ See *Vita-Mix*, 581 F.3d at 1328.

¹¹⁰ See *Paradkar & Park*, *supra* note 14.

¹¹¹ See *id.*

act.¹¹² Much like *Akamai's* theory of divided infringement, through which only the operating entity may be held liable because it is the only entity that can be said to direct or control end users' performance by providing the use instructions,¹¹³ inducement limits patent owners to holding only the operating entity liable because the affirmative act of inducement can only be evidenced through the instructions provided by the operating entity.¹¹⁴ Because the affirmative act of inducement for patent infringement by AI requires manufacturing entities to take affirmative steps in persuading or influencing the end users' infringing performance,¹¹⁵ other entities that contributed to the AI cannot be held liable for the infringement, as they do not have any interaction with end users that could constitute an affirmative act of inducement.

For a cause of action under contributory infringement, another difficulty for patent owners is proving that a machine learning system is a component under the meaning of the statute.¹¹⁶ Similar to Microsoft's master copy,¹¹⁷ the subscription use of AI is not likely to be a "component," as it is not given to end users on a computer readable medium and therefore is unlikely to be considered a physical copy amenable to combination with a computer.¹¹⁸ Furthermore, compared to § 271(f)'s "component of a patented invention," § 271(c)'s "component of a patented machine, manufacture, combination, or composition" applies to a narrower category, making it likely that it will have an even narrower meaning.¹¹⁹ Since AI is not likely to constitute a component under § 271(c), AI manufacturers cannot be held liable under contributory infringement.

4. Implications of the Doctrinal Gaps in the Patent Infringement Statute for AI

Section 271 fails to assign liability to all manufacturing entities that are responsible when their AI infringes a patent. Under § 271(a) direct infringement, a single entity must perform all the steps of a method patent to infringe, so the liability falls on the end user, as none of the manufacturing entities perform the final step of input of data.¹²⁰ Solely assigning liability to end users in direct infringement is problematic because customers often lack the technical

¹¹² See Kimberly A. Moore, et al., *Patent Litigation and Strategy* 445 (West 5th ed. 2018).

¹¹³ See discussion *supra* Section II.A.2.

¹¹⁴ See discussion *supra* Section I.D.; *cf. Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc).

¹¹⁵ See MOORE ET AL., *supra* note 112, at 444.

¹¹⁶ See 35 U.S.C. § 271(c).

¹¹⁷ See *Microsoft Corp. v. A T & T Corp.*, 550 U.S. 437, 442 (2007).

¹¹⁸ See *id.* at 449; discussion *supra* Section I.D.

¹¹⁹ 35 U.S.C. §§ 271(f), 271(c).

¹²⁰ See discussion *supra* Section II.A.1.

knowledge to foresee infringement, especially if they are individuals and not sophisticated corporations.¹²¹ The possibility of being held liable for the use of AI may lead to consumer disuse of otherwise helpful AI and decrease investment and innovation in an industry with such great potential.¹²² In addition, infringed patent owners would receive inadequate relief, as they would not be able to receive damages or ongoing royalties from manufacturing entities and would only be compensated to the extent of individual customer use.¹²³

Under *Akamai* divided infringement, only the operating entity may be held liable, as the other manufacturing entities lack the requisite interaction with end users to amount to direction and control.¹²⁴ Under § 271(b) and (c) indirect infringement, manufacturing entities cannot be held liable because the requisite intent and knowledge are contrary to the automatic-updating ability of AI.¹²⁵ The failure to assign liability to all responsible manufacturing entities in divided and indirect infringement is a concern because if the law does not hold manufacturing entities accountable, inventors and corporations in the software and AI industries will lose confidence in their ability to profit from their inventions and both commercialization efforts and the industries will falter from the resulting decrease in innovation and investment.¹²⁶

Although patent infringement disputes relating to AI may not be as palpable as other AI suits that involve physical injuries,¹²⁷ effective protection and enforcement of patent rights is essential to encourage inventive activity and further technological and societal advancement.¹²⁸ By granting limited exclusive rights and preventing others' imitation during the patent term, patent rights incentivize inventors' public disclosure and implementation of

¹²¹ See Kay Firth-Butterfield & Yoon Chae, *Artificial Intelligence Collides with Patent Law*, WORLD ECONOMIC FORUM CENTER FOR THE FOURTH INDUSTRIAL REVOLUTION 11 (April 2018), https://www3.weforum.org/docs/WEF_48540_WP_End_of_Innovation_Protecting_Patent_Law.pdf [<https://perma.cc/P9MJ-7FMJ>].

¹²² See *id.*

¹²³ See *id.*

¹²⁴ See discussion *supra* Section II.A.2.

¹²⁵ See discussion *supra* Section II.A.3.

¹²⁶ See Bronwyn H. Hall, *Patents and Patent Policy*, 23 OXFORD REV. ECON. POL'Y 568, 568, 571–72 (2007).

¹²⁷ See, e.g., *Holbrook v. Prodmax Automation, Ltd.*, No. 17-cv-00219, 2020 U.S. Dist. LEXIS 207134, at *1 (W.D. Mich. Nov. 5, 2020); Conner Forrest, *Robot Kills Worker on Assembly Line, Raising Concerns About Human-Robot Collaboration*, TECHREPUBLIC (Mar. 15, 2017, 10:15 AM), <https://www.techrepublic.com/article/robot-kills-worker-on-assembly-line-raising-concerns-about-human-robot-collaboration/> [<https://perma.cc/5C3M-YU55>] (stating that a car plant employee Wanda Holbrook was killed on the job when an assembly robot malfunctioned by bypassing safety regulations and entering an unauthorized area).

¹²⁸ See Hall, *supra* note 126, at 571–72.

inventions and allow others to build upon their disclosures for further innovation.¹²⁹ If the law fails to redress the infringement of software and AI patents and protect the rights of patent owners in those industries, inventors and corporations will be less willing to make disclosures or invest in commercialization because of uncertainty in their ability to enforce their legal rights and exclude others from making or using their invention in return.¹³⁰

Furthermore, if the law fails to hold manufacturing entities accountable for the actions and infringements of their AI, manufacturing entities will no longer be incentivized to take precautions in training and operating AI, resulting in a greater amount of patent infringement in the near future.¹³¹ By failing to assign liability, the legal system will fail to police inventors' and corporations' behaviors and instead allow them to take advantage of the lack of accountability by devoting less resources to preventing patent infringement by their AI inventions.¹³² Although divided infringement may hold operating entities liable, unless all the responsible manufacturing entities are held accountable, other manufacturing entities will face the incentive to cheat and freeride off operating entities, and the operating entities will be unfairly penalized for the collective product from all the manufacturing entities. To prevent the software and AI industries from faltering with decreased innovation and increased patent infringement, the law must hold all involved manufacturing entities accountable. Because the patent infringement statute¹³³ is insufficient in achieving that goal alone, legal doctrines outside the scope of patent law must be considered.

B. Current Applications of Corporate Law Fail to Fill the Liability Gap in the Patent Infringement Statute for AI Systems

1. Respondeat Superior Doctrine

If corporations are held liable for the actions or algorithms taken by their AI, they, as the “least-cost avoider,” will be incentivized to take the optimal levels of precaution in developing AI and preventing any patent infringement caused by their AI.¹³⁴ For AI systems like machine learning, however, the logic for the attribution of algorithmic action to employee action wears thin because complex AI continually learns from input of end users' data and

¹²⁹ See *id.* at 568, 572.

¹³⁰ See *id.* at 568, 571–72.

¹³¹ See *Diamantis*, *supra* note 63, *passim*.

¹³² See *id.* at 853.

¹³³ 35 U.S.C. § 271 (2018).

¹³⁴ See *Diamantis*, *supra* note 63, at 816.

automatically updates its own algorithms.¹³⁵ The resulting infringing algorithm is less like an algorithm-enabled automated action of an employee and more like an independent action taken by the algorithm itself. Unlike traditional programming, in which humans write every line of code and algorithms operate under concrete rules set by humans, complex AI systems operate by correcting programmers' initial input of learning algorithm and integrating every new entry of data.¹³⁶

While simple, piecewise, and constant algorithms may constitute employee action,¹³⁷ more complex AI systems, especially machine learning systems, that unpredictably conduct automatic updates to its algorithms from new data cannot be attributed to employee action. Unlike the price-setting Amazon Marketplace algorithms in *Topkins*, which involved simple and step-wise commands for algorithms to match lowered prices,¹³⁸ complex AI systems' automatic updates that incorporate new data and rewrite codes are not a mere automation of employees' actions.¹³⁹ Rather, these actions are taken solely by AI, independent of any employee's direction.¹⁴⁰ Therefore, in complex AI systems—where AI itself guides its owns actions in writing the infringing algorithm—AI actions cannot be equated to employees' actions.¹⁴¹ For this reason, the existing application of the *respondeat superior* doctrine fails to hold corporations liable for their AI's patent infringement.

2. Products Liability

Products liability focuses on the nature of the product rather than the nature of the manufacturer's conduct.¹⁴² If applied to patent infringement by AI, products liability would allow patent owners to seek redress despite their inability to trace algorithmic actions to manufacturers' actions and provide evidentiary support of manufacturers' fault.¹⁴³ However, the problem in applying products liability to patent infringement is that products liability

¹³⁵ See Surden, *supra* note 21, at 89; INFO. COMM'RS OFF., BIG DATA, ARTIFICIAL INTELLIGENCE, MACHINE LEARNING AND DATA PROTECTION 7 (2017) <http://www.ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf>.

¹³⁶ See Catherine Tremble, Note, *Wild Westworld: Section 230 of the CDA and Social Networks' Use of Machine-Learning Algorithms*, 86 FORDHAM L. REV. 825, 837 (2017).

¹³⁷ See discussion *supra* Section I.E.

¹³⁸ See Plea Agreement at 4, *United States v. Topkins*, No. CR 15-00201 (N.D. Cal. 2015).

¹³⁹ See Surden, *supra* note 21, at 94.

¹⁴⁰ See *id.*

¹⁴¹ See *id.*

¹⁴² See RESTATEMENT (SECOND) OF TORTS § 402A(1) (explaining that strict liability applies to products liability even if "the seller has exercised all possible care . . .").

¹⁴³ See Diamantis, *supra* note 63, at 823.

is designed to apply only for harm to the ultimate user or consumer.¹⁴⁴ In the AI patent infringement context, the ultimate user and consumer are the end users of AI systems,¹⁴⁵ but they are not the ones that are harmed; it is the patent owner's intellectual property rights that are infringed. While some states have allowed bystanders to sue under a products liability theory,¹⁴⁶ most states still limit products liability standing to users and consumers,¹⁴⁷ so it seems unlikely that courts will be amenable to further expanding the standing requirement to include patent owners. As such, patent owners do not have standing to bring infringement actions under products liability, and products liability cannot hold AI manufacturers liable for patent infringement by their AI inventions.

III. Recommendation: Extension of the *Respondeat Superior* Doctrine

To hold manufacturing entities liable for patent infringement by their AI, the Federal Circuit should adopt a federal common law principle that recognizes algorithmic action as corporate action, just as the existing application of the *respondeat superior* doctrine has equated employee action to corporate action. Although equating algorithmic action to corporate action moves beyond the existing application of *respondeat superior*, doing so aligns with the core principles of control and benefits, thereby justifying its extended application to AI systems.¹⁴⁸ Unlike the solutions of equating algorithmic action to employee action or expanding products liability standing to patent owners, this solution requires neither a disregard for the technological complexities of AI systems nor an uprooting of basic legal principles.¹⁴⁹ By expanding the fictional personhood of corporations and definition of corporate agents beyond

¹⁴⁴ See RESTATEMENT (SECOND) OF TORTS § 402A(1) (“[E]xpresses no opinion as to whether [strict products liability] appl[ies] . . . to harm to persons other than users or consumers”).

¹⁴⁵ Cf. *supra* notes 83–90 and accompanying text (outlining the role of an AI end user in potential direct infringement liability); *supra* notes 119–22 and accompanying text (identifying consumers as the end users of AI systems).

¹⁴⁶ See IND. CODE § 34-6-2-29 (2020) (allowing “any bystander injured by the product who would reasonably be expected to be in the vicinity of the product during its reasonably expected use” to bring suit under products liability).

¹⁴⁷ See, e.g., *Woods v. Fruehauf Trailer Corp.*, 765 P.2d 770, 774 (Okla. 1988); *Rohrbaugh v. Owens-Corning Fiberglas Corp.*, 965 F.2d 844, 846 (10th Cir. 1992)); *Lunsford v. Saberhagen Holdings, Inc.*, 106 P.3d 808, 812 (Wash. Ct. App. 2005), *aff'd*, 208 P.3d 1092 (Wash. 2009).

¹⁴⁸ See *Diamantis*, *supra* note 63, at 827.

¹⁴⁹ See *id.*

the bodies and minds of employees, this solution leverages the foundations of corporate law to recognize AI systems as independently cognizable agents¹⁵⁰ while avoiding issues that arise from recognizing AI systems as legal entities capable of acting independently or as mere tools subject to absolute control.

Just as the current application of the *respondeat superior* doctrine holds corporations liable for employee actions that are within the corporation's control and that benefit the corporation,¹⁵¹ the proposed application of *respondeat superior* will hold corporations liable for AI algorithmic actions that are within the corporation's control and that benefit the corporation. For the benefits aspect, the *respondeat superior* doctrine requires employees to act in furtherance of the corporation's purpose.¹⁵² For AI systems like machine learning, manufacturing entities train the algorithm to reach a certain end goal;¹⁵³ if AI reaches the desired capacity, even if it conducts the tasks through unanticipated infringing algorithms, it acts for the benefit of the corporation. For the control aspect, the *respondeat superior* doctrine requires the employee's actions to be within the scope of their employment in order to be equated to corporate action.¹⁵⁴ Although complex AI systems act autonomously to update their codes,¹⁵⁵ human employees act unpredictably within the scope of their employment.¹⁵⁶ Nonetheless, the law holds corporations liable for unpredictable employee actions so long as prevention was possible through proper training and discipline of their employees.¹⁵⁷ AI manufacturers should likewise be held accountable to the extent that their failure to take preventive measures results in AI's patent infringement. These preventive measures include "diversifying the body of engineers writing algorithms, more careful initial programming, more mindful selection of data sets, more extensive pre-rollout testing, regular post-rollout quality audits, routine runtime compliance layers, effective monitoring, and continuous software updates to address problems as they arise."¹⁵⁸ Courts may use these measures as a proxy for determining the level of control manufacturing entities have over AI systems.¹⁵⁹

By recognizing corporate algorithms as a part of the body corporate, patent infringement committed by AI systems can be recognized as the acts of manufacturing entities under direct infringement from the use of patented methods

¹⁵⁰ See *id.* at 828.

¹⁵¹ See *United States v. Hilton Hotels Corp.*, 467 F.2d 1000, 1004 (9th Cir. 1972).

¹⁵² See *id.*

¹⁵³ See *Semmler & Rose*, *supra* note 18, at 87.

¹⁵⁴ See *Hilton Hotels Corp.*, 467 F.2d at 1004.

¹⁵⁵ See *Surden*, *supra* note 21, at 94.

¹⁵⁶ See *Davis-Lynch, Inc. v. Asgard Techs., LLC*, 472 S.W.3d 50, 72 (Tex. App. 2015).

¹⁵⁷ See *id.*

¹⁵⁸ *Diamantis*, *supra* note 63, at 833–34.

¹⁵⁹ See *id.*

as defined in § 271(a).¹⁶⁰ Because extension of the *respondeat superior* doctrine allows AI systems to be recognized as independently cognizable agents of manufacturing corporations, AI itself would be using a patented method claim and violating § 271(a). Under the current law, AI manufacturers cannot be held liable under direct infringement because a single entity must perform all the steps of a claimed method and no single manufacturer performs all the steps.¹⁶¹ However, by recognizing AI inventions as agents of corporations, AI itself can be recognized as performing all the steps of a claimed method and be held liable for direct infringement. Following the extended application of the *respondeat superior* doctrine, the infringing acts of AI can then be attributed to its principal, the manufacturing corporations, to the extent that the manufacturing entities had the ability to enforce preventative measures.¹⁶²

As *respondeat superior* is a common law doctrine introduced to corporate law and expanded through judicial decisions,¹⁶³ the Federal Circuit can extend the doctrine to equate algorithmic action to corporate action and hold corporations liable for their algorithms, just as courts now freely accept corporations' liability for their employees.¹⁶⁴ In the past, corporate productive capacity was expanded by hiring employees, so corporations only needed to be held accountable to the extent of their employees' actions.¹⁶⁵ Now, algorithms are replacing human employees and acting autonomously in ways that humans do,¹⁶⁶ and yet, the law fails to attribute algorithmic faults to manufacturing corporations. In order to prevent the software and AI industries from faltering with decreased innovation and increased patent infringement, the law must hold all involved manufacturing entities accountable for infringing actions by AI. To do so, the Federal Circuit should extend the *respondeat superior* doctrine to algorithmic actions and hold manufacturing corporations liable for the infringing actions of their AI.

¹⁶⁰ See 35 U.S.C. § 271(a).

¹⁶¹ See discussion *supra* Section II.A.1.

¹⁶² See Diamantis, *supra* note 63, at 847.

¹⁶³ See *Packard Motor Car Co. v. NLRB*, 330 U.S. 485, 489 (1947); Daniel L. Cheyette, *Policing the Corporate Citizen: Arguments for Prosecuting Organizations*, 25 ALASKA L. REV. 175, 179–80 (2008).

¹⁶⁴ See, e.g., *Connick v. Thompson*, 563 U.S. 51, 62 (2011); *Scottsdale Ins. Co. v. Subscription Plus, Inc.*, 299 F.3d 618, 621 (7th Cir. 2002).

¹⁶⁵ See Aaron Smith & Monica Anderson, *Americans' Attitudes Toward a Future in Which Robots and Computers Can Do Many Human Jobs*, PEW RSCH. CTR. (Oct. 4, 2017), <https://www.pewresearch.org/internet/2017/10/04/americans-attitudes-toward-a-future-in-which-robots-and-computers-can-do-many-human-jobs/> [<https://perma.cc/RK9B-ABBL>].

¹⁶⁶ See *id.*

Conclusion

Premised in the grant of limited exclusive rights over an invention in exchange for the invention's disclosure to the rest of the world, patent rights would mean little, if anything, without effective enforcement preventing others from imitation during the patent owner's term. Furthermore, if the law fails to hold manufacturing entities accountable for their AI, nothing will prevent them from taking advantage of the loophole and devoting little, if any, resources to the policing of their products. To prevent chaos within the software and AI industries, courts must find a way to hold manufacturing entities liable for patent infringement by their AI. Because the autonomous coding ability of AI does not align with the existing causes of action under the patent infringement statute, the Federal Circuit should look to the *respondeat superior* doctrine and extend the corporate body to include algorithmic actions, thereby holding corporations accountable for their AI.

“Out of This World” Litigation Has Down-to-Earth Repercussions: Blue Origin’s Bid Protest Loss and the Paradox of Applying Conventional Procedural Constraints to Unconventional Space Procurements

Sabrina Stantzyk-Guzek*

Introduction

The saying “Don’t tell me the sky’s the limit when there are footprints on the moon” has been taken to a whole new level as billionaires Jeff Bezos and Elon Musk continue to battle over the moon—specifically, moon landers.¹ On April 16, 2021, NASA awarded a sole contract to Musk’s company SpaceX for the development of its lunar lander as part of NASA’s mission to land “the first woman and next man on the Moon by 2024.”² While NASA’s original preference was to select two companies for its mission—to encourage both

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¹ Paul Brandt, *There’s a World Out There, on THAT’S THE TRUTH* (Time Warner 1999); see also Christian Davenport, *Jeff Bezos Challenges NASA Moon-Contract Award to Elon Musk’s SpaceX*, WASH. POST (Apr. 26, 2021, 9:32 PM), <https://www.washingtonpost.com/technology/2021/04/26/jeff-bezos-challenges-nasa-moon-contract-award-elon-musks-spacex/> [https://perma.cc/QT8P-SNAU]. Moon landers, also referred to as lunar landers, are spacecrafts “designed to land on the surface of the moon.” *What Is a Lunar Lander? Learn How the Apollo Lunar Module Was Designed*, MASTERCLASS (Sept. 28, 2021), <https://www.masterclass.com/articles/what-is-a-lunar-lander> [https://perma.cc/YFD6-7RSH].

² NAT’L AERONAUTICS & SPACE ADMIN., ARTEMIS PLAN: NASA’S LUNAR EXPLORATION PROGRAM OVERVIEW 13 (2020), https://www.nasa.gov/sites/default/files/atoms/files/artemis_plan-20200921.pdf [https://perma.cc/3A6T-ZSWF] [hereinafter ARTEMIS PLAN OVERVIEW]; see NAT’L AERONAUTICS & SPACE ADMIN., NNH19ZCQ001K_APPENDIX-H-HLS, SOURCE SELECTION STATEMENT 2 (2021), <https://www.nasa.gov/sites/default/files/>

competition and innovation—the agency ultimately selected only one company due to budgetary constraints.³ NASA’s decision to select SpaceX came as a surprise to many commentators who originally viewed Bezos’s company Blue Origin as a front-runner in the competition for the contract, especially after the company assembled a team of major twentieth-century leaders in the spaceflight contracting business to help develop its lunar lander.⁴

Blue Origin protested the award in the U.S. Government Accountability Office (“GAO”) and the United States Court of Federal Claims (“CoFC”), which both ultimately supported NASA’s decision to award the contract to SpaceX.⁵ While both forums made it appear as if Blue Origin had no chance at prevailing due to conventional legal barriers—and critics complained that Bezos sued on behalf of Blue Origin for solely selfish reasons—maybe Bezos was upset for some of the right reasons after all.⁶

Part I of this Note will detail the background of NASA’s Human Landing System (“HLS”) solicitation and outline the legal determinations in a bid protest. Part II will analyze weaknesses and strengths of Blue Origin’s claims, raising concern over whether both bid protest forums should have applied conventional procedural barriers to claims concerning unpredictable space matters. Finally, Part III will suggest that future bid protest officials⁷ should carve out legal exceptions for protests involving issues of safety, especially as commercial companies continue to exceed NASA’s technical expertise.

atoms/files/option-a-source-selection-statement-final.pdf [https://perma.cc/XA7K-BVD9] [hereinafter SOURCE SELECTION STATEMENT].

³ See SOURCE SELECTION STATEMENT, *supra* note 2, at 13.

⁴ See Jeff Foust, *Blue Origin, Lockheed, Northrop Join Forces for Artemis Lunar Lander*, SPACE NEWS (Oct. 22, 2019), <https://spacenews.com/blue-origin-lockheed-northrop-join-forces-for-artemis-lunar-lander/> [https://perma.cc/U8EX-92PQ] [hereinafter Foust, *Blue Origin, Lockheed, Northrop Join Forces for Artemis Lunar Lander*]; see also Davenport, *supra* note 1.

⁵ See *Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al.*, 2021 CPD ¶ 265, at 76 (Comp. Gen. July 30, 2021); see also *Blue Origin Fed’n, LLC v. United States*, 157 Fed. Cl. 74, 81, 113–14 (2021).

⁶ See, e.g., Jianli Yang, Opinion, *Jeff Bezos’ Greed Could Cost the U.S. the Moon*, WASH. TIMES (Nov. 22, 2021), <https://www.washingtontimes.com/news/2021/nov/22/jeff-bezos-greed-could-cost-the-us-the-moon/> [https://perma.cc/QW64-TW5Y].

⁷ As used in this article, the phrase “bid protest officials” collectively refers to presiding counsel at the GAO and the presiding judges at the CoFC and the United States Court of Appeals for the Federal Circuit.

I. Background: NASA’s HLS Mission

A. Private Sector Innovation

NASA is the U.S. government agency responsible for space research and exploration.⁸ However, with the evolution of the new space age, NASA has shifted many of its roles and responsibilities to private companies who have a greater tolerance for the economic risk of investing in space.⁹ As stated by NASA itself, “Private sector innovation is key to NASA’s goal of sustainable lunar exploration[,] and the agency’s many public-private partnerships are already advancing capabilities for human spaceflight in deep space while stimulating commercial activities.”¹⁰

B. NASA’s HLS Solicitation

In its new era of space exploration, one of NASA’s current missions is to “land the first woman and first person of color on the Moon.”¹¹ This mission is titled “The Artemis Plan.”¹² Among multiple components needed to facilitate this plan—including the Space Launch System Rocket (“SLS Rocket”), Orion spacecraft, and exploration ground systems—is the development of a Human Landing System (“HLS”) that will transport astronauts to the lunar surface.¹³ As described on NASA’s website, “Built by American companies, human landing systems are the final mode of transportation that will take astronauts from lunar orbit to the surface and back to orbit.”¹⁴

⁸ See *About NASA*, NAT’L AERONAUTICS & SPACE ADMIN., <https://www.nasa.gov/about/index.html> [<https://perma.cc/FTJ4-VSKR>] (last visited Oct. 4, 2022).

⁹ See Christian Davenport, *As Private Companies Erode Government’s Hold on Space Travel, NASA Looks to Open a New Frontier*, WASH. POST (Feb. 25, 2021, 6:00 AM), <https://www.washingtonpost.com/technology/2021/02/25/nasa-space-future-private/> [<https://perma.cc/2YSK-WDZZ>]; Matt Weinzierl & Mehak Sarang, *The Commercial Space Age Is Here*, HARV. BUS. REV. (Feb. 12, 2021), <https://hbr.org/2021/02/the-commercial-space-age-is-here> [<https://perma.cc/56CF-99WJ>].

¹⁰ *NASA Seeks Input from U.S. Industry on Artemis Lander Development*, NAT’L AERONAUTICS & SPACE ADMIN. (July 22, 2019), <https://www.nasa.gov/feature/nasa-seeks-input-from-us-industry-on-artemis-lander-development> [<https://perma.cc/GAZ5-Q773>].

¹¹ *Artemis*, NAT’L AERONAUTICS & SPACE ADMIN., <https://www.nasa.gov/specials/artemis/> [<https://perma.cc/6UST-ASYM>] (last visited Oct. 7, 2022).

¹² See *id.*

¹³ See *id.*; *As Artemis Moves Forward, NASA Picks SpaceX to Land Next Americans on Moon*, Release 21-042, NAT’L AERONAUTICS & SPACE ADMIN. (Apr. 16, 2021), <https://www.nasa.gov/press-release/as-artemis-moves-forward-nasa-picks-spacex-to-land-next-americans-on-moon> [<https://perma.cc/34N8-7YCS>]; see also *More About the Human Landing System Program*, NAT’L AERONAUTICS & SPACE ADMIN. (Sept. 22, 2020), <https://www.nasa.gov/content/more-about-the-human-landing-system-program> [<https://perma.cc/RAW8-SP5D>].

¹⁴ *Artemis*, *supra* note 11.

In 2018, NASA began its acquisition process for commercially provided landing systems by releasing a solicitation under Appendix E of its Next Space Technologies for Exploration Partnerships (NextSTEP-2) Broad Agency Announcement (“BAA”)—a type of competitive procedure governed by the Federal Acquisition Regulation (“FAR”).¹⁵ As described in FAR 35.016(a):

BAA’s may be used by agencies to fulfill their requirements for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. The BAA technique shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.¹⁶

Only one day after proposals were received on March 25, 2019, former Vice President Mike Pence had a change of mind for the agency.¹⁷ While speaking at the National Space Council’s March meeting, Pence instructed NASA to use “any means necessary” to expedite its plans so that humans would land on the Moon by a new deadline of 2024—instead of its original deadline of 2028—in response to anticipated rivalry from China and Russia.¹⁸ Within two months, NASA selected eleven companies under NextSTEP-2 Appendix E contracts to study and produce prototypes of reduced-risk human landing systems.¹⁹ The eleven companies selected included Aerojet Rocketdyne, Boeing, Dynetics, Lockheed Martin, Masten Space Systems, Northrop Grumman Innovation Systems, OrbitBeyond, Sierra Nevada Corporation, and SSL, in addition to the billionaire-owned companies Blue Origin and SpaceX.²⁰

As part of its efforts to expedite its moon plan, in July 2019, NASA issued a draft solicitation under Appendix H of its NextSTEP-2 BAA.²¹ This draft

¹⁵ See ARTEMIS PLAN OVERVIEW, *supra* note 2, at 12–13; see also *NextSTEP E: Human Landing System Studies, Risk Reduction, Development, and Demonstration*, NAT’L AERONAUTICS & SPACE ADMIN. (Mar. 29, 2022), <https://www.nasa.gov/nextstep/humanlander> [<https://perma.cc/DC78-RMHS>].

¹⁶ FAR 35.016(a) (2021).

¹⁷ See ARTEMIS PLAN OVERVIEW, *supra* note 2, at 12–13; see, e.g., Jeff Foust, *Pence Calls for Human Return to the Moon by 2024*, SPACE NEWS (Mar. 26, 2019), <https://spacenews.com/pence-calls-for-human-return-to-the-moon-by-2024/> [<https://perma.cc/FJ47-4RW7>] [hereinafter Foust, *Pence Calls for Human Return to the Moon by 2024*].

¹⁸ Foust, *Pence Calls for Human Return to the Moon by 2024*, *supra* note 17.

¹⁹ See ARTEMIS PLAN OVERVIEW, *supra* note 2, at 13.

²⁰ See *NASA Taps 11 American Companies to Advance Human Lunar Landers*, Release 19-040, NAT’L AERONAUTICS & SPACE ADMIN. (May 16, 2019), <https://www.nasa.gov/press-release/nasa-taps-11-american-companies-to-advance-human-lunar-landers> [<https://perma.cc/GJ2T-GZ5Z>].

²¹ See ARTEMIS PLAN OVERVIEW, *supra* note 2, at 13; see also NAT’L AERONAUTICS & SPACE ADMIN., NNH19ZCQ001K_APPENDIX-H-HLS, BROAD AGENCY ANNOUNCEMENT 5 (2019) [hereinafter APPENDIX H BROAD AGENCY ANNOUNCEMENT].

set forth a multi-phase procurement approach to promote prompt HLS development and demonstrations and sought feedback from industry companies interested in developing and demonstrating an integrated HLS to place humans on the moon by 2024.²² After issuing another draft, addressing many comments, and issuing the final Appendix H solicitation, NASA began its procurement in the spring of 2020 by awarding three base period contract awards to Blue Origin, SpaceX, and Dynetics for the design and development of their proposed landing systems.²³ The awards were “firm-fixed price, milestone-based contracts” with a collective value of \$967 million for a ten-month base period.²⁴ SpaceX’s plan was to develop a one-element lander called the Starship that would require sixteen launches, while Blue Origin’s plan was to develop a three-element lander called the Integrated Lander that would require three launches.²⁵ As part of Blue Origin’s team, Lockheed Martin, Northrop Grumman, and Draper were to each develop different parts of the landing system.²⁶

C. NASA’s Amended Option A HLS Solicitation

While the three contractors were performing under their base period contracts, NASA conducted the next phase of the HLS procurement by issuing an Option A BAA solicitation followed by an amended Option A Appendix H solicitation, which stated that up to two contractors could be awarded Option A contract line item numbers (“CLINs”)²⁷ to continue development of the landing system.²⁸ NASA also noted that it reserved the right “to select for award multiple, one, or none of the proposals received in response to this Appendix” and the number of awards given would depend on “funding availability and evaluation results.”²⁹ Further, NASA reserved the right to conduct post-selection negotiations with one or more offerors, which it defined

²² See ARTEMIS PLAN OVERVIEW, *supra* note 2, at 13; see also APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 5.

²³ See *NASA Names Companies to Develop Human Landers for Artemis Moon Missions*, Release 20-048, NAT’L AERONAUTICS & SPACE ADMIN. (Apr. 30, 2020), <https://www.nasa.gov/press-release/nasa-names-companies-to-develop-human-landers-for-artemis-moon-missions> [<https://perma.cc/U2J8-2GYC>] [hereinafter Release 20-048].

²⁴ *Id.*

²⁵ See *Blue Origin Fed’n, LLC v. United States*, 157 Fed. Cl. 74, at 84 (2021).

²⁶ See Foust, *Blue Origin, Lockheed, Northrop Join Forces for Artemis Lunar Lander*, *supra* note 4.

²⁷ CLINs are parts of federal procurement contracts that break down the supplies or services to be acquired in the contract into separately identified line items. See FAR 4.1001 (2021).

²⁸ See APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 8–9.

²⁹ *Id.* at 57.

as “exchanges with Offerors who have been selected for potential contract award that do not contemplate material proposal revisions and are intended to address outstanding contract terms and conditions.”³⁰

NASA also claimed it would not compare proposals consistent with FAR 35.016(d), which states that proposals received as a result of a BAA do not need to be evaluated against each other.³¹ This rule stems from the fact that requirements for proposals in a BAA procurement are generally not submitted in accordance with a common Statement of Work (“SOW”)—a document providing a baseline description of the work to be performed under a contract against which a contractor’s performance is measured—because BAAs are not based on common specifications for existing equipment but instead on new research and development solutions.³² NASA attached a SOW to the solicitation nonetheless.³³ Among other specifications, the SOW detailed the major milestone review requirements to be met by the contractors.³⁴ Relevant to the HLS procurement, the specifications included a requirement that mandated Flight Readiness Reviews (“FRRs”)—reviews “designed to determine the system’s readiness for a safe and successful flight or launch and for subsequent flight operations”—to be completed two weeks before the launch of each HLS element.³⁵

NASA’s solicitation also stated that its primary basis for award selection was a combination of “technical [rating], importance to Agency programs, and funds availability,” in alignment with FAR 35.016(e), under three main

³⁰ *Id.* at 12, 14.

³¹ *See id.* at 50; *see also* FAR 35.016(d) (2021). FAR 35.016(d) reads,

Proposals received as a result of the BAA shall be evaluated in accordance with evaluation criteria specified therein through a peer or scientific review process. Written evaluation reports on individual proposals will be necessary but proposals need not be evaluated against each other since they are not submitted in accordance with a common work statement.

Id.

³² *See* Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos, B-419783 et al., 2021 CPD ¶ 265, at 32 (Comp. Gen. July 30, 2021) (citing Wang Electro-Opto Corp., B-418523, 2020 CPD ¶ 187, at 5 (Comp. Gen. June 4, 2020); Kolaka No’eau, Inc., B-291818, 2003 CPD ¶ 67, at 5-6 (Comp. Gen. Apr. 2, 2003); INRAD, Inc., B-284021, 2021 CPD ¶ 239, at 3 (Comp. Gen. Feb. 4, 2000)). *See generally* RALPH NASH ET AL., THE GOVERNMENT CONTRACTS REFERENCE BOOK (5th ed., 2021).

³³ *See* APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 15. *See generally* FAR 35.005 (2021).

³⁴ *See* NAT’L AERONAUTICS & SPACE ADMIN., NNH19ZCQ001K_APPENDIX-H-HLS, BAA ATTACHMENT G: STATEMENT OF WORK (SOW) 19–33 (2019).

³⁵ *Id.* at 29.

evaluation factors.³⁶ The first evaluation factor was technical approach, which included areas of focus such as technical design concept; development, schedule, and risk; verification, validation, and certification; insight; launch and mission operations; sustainability; and approach to early system demonstrations.³⁷ The second factor was total evaluated price, and the third factor was management approach, which included areas of focus such as organization and management, schedule management, risk reduction, commercial approach, base period performance, small business subcontracting plan, and data rights.³⁸

Table 1. Option A Evaluation Factors and Areas of Focus³⁹

Evaluation Factor	Area of Focus
Factor 1: Technical Approach	Technical Design Concept Development, Schedule, and Risk Verification, Validation, and Certification Insight Launch and Mission Operations Sustainability Approach to Early System Demonstrations
Factor 2: Total Evaluated Price	No focus areas
Factor 3: Management Approach	Organization and Management Schedule Management Risk Reduction Commercial Approach Base Period Performance Small Business Subcontracting Plan Data Rights

These factors were evaluated based on adjectival ratings descending in the following order: Outstanding, Very Good, Acceptable, Marginal, and Unacceptable.⁴⁰

³⁶ APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 50–52; *see also* FAR 35.016(e) (2021) (“The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate.”).

³⁷ *See* APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 52.

³⁸ *See id.*

³⁹ SOURCE SELECTION STATEMENT, *supra* note 2, at 5.

⁴⁰ *See* APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 53.

Table 2. Option A Adjectival Ratings Definitions⁴¹

Adjectival Rating	Definition
Outstanding	A thorough and compelling proposal of exceptional merit that fully responds to the objectives of the BAA. Proposal contains strengths that far outweigh any weaknesses.
Very Good	A competent proposal of high merit that fully responds to the objectives of the BAA. Proposal contains strengths which outweigh any weaknesses.
Acceptable	A competent proposal of moderate merit that represents a credible response to the BAA. Strengths and weaknesses are offsetting or will have little or no impact on contract performance.
Marginal	A proposal of little merit. Proposal does not clearly demonstrate an adequate approach to and understanding of the BAA objectives. Weaknesses outweigh strengths.
Unacceptable	A seriously flawed proposal that is not responsive to the objectives of the BAA. The proposal has one or more deficiencies, or multiple significant weaknesses that either demonstrate a lack of overall competence or would require a major proposal revision to correct. The proposal is unawardable.

Within the non-price factors, NASA would also identify and evaluate strengths and weaknesses by considering “how an Offeror’s proposed approach affects risks, such as technical risk, risk to meeting schedule requirements, the need for increased Government oversight, or the risk of likelihood of unsuccessful contract performance.”⁴²

Table 3. Option A Findings Definitions⁴³

Finding	Definition
Significant Strength	An aspect of the proposal that greatly enhances the potential for successful contract performance and/or that appreciably exceeds specified performance or capability requirements in a way that will be advantageous to the Government during contract performance.
Strength	An aspect of the proposal that will have some positive impact on the successful performance of the contract and/or that exceeds specified performance or capability requirements in a way that will be advantageous to the Government during contract performance.
Weakness	A flaw in the proposal that increases the risk of unsuccessful contract performance.
Significant Weakness	A flaw in the proposal that appreciably increases the risk of unsuccessful contract performance.
Deficiency	A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

⁴¹ SOURCE SELECTION STATEMENT, *supra* note 2, at 6.

⁴² APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 52.

⁴³ SOURCE SELECTION STATEMENT, *supra* note 2, at 5.

When combined, the non-price factors were supposed to be considerably more important than the total evaluated price in determining whose proposal was of sufficient value to the agency.⁴⁴

D. NASA’s HLS Contract Award

Following receipt of the Option A Appendix H proposals from the three companies, a Source Evaluation Panel (“SEP”) comprised of NASA subject-matter experts evaluated each proposal based on the aforementioned factors.⁴⁵ For the technical approach factor, SpaceX and Blue Origin received an “Acceptable” rating and Dynetics received a “Marginal” rating.⁴⁶ For the management factor, SpaceX received an “Outstanding” rating, and Blue Origin and Dynetics received a “Very Good” rating.⁴⁷ For the price factor, SpaceX offered \$2,941,394,557, Blue Origin offered \$5,995,463,651, and Dynetics offered \$9,082,209,433.⁴⁸ In regards to strengths and weaknesses, each proposal possessed ranging weaknesses.⁴⁹ However, NASA declined to designate any of the weaknesses as material failures—not even SpaceX’s failure to meet the FRR milestone requirements, which the SEP noted “increased the risk of unsuccessful contract performance.”⁵⁰

Table 4. Option A Technical Management Adjectival Ratings⁵¹

	Technical Rating (Factor 1)	Management Rating (Factor 3)
Blue Origin	Acceptable	Very Good
Dynetics	Marginal	Very Good
SpaceX	Acceptable	Outstanding

Finding value in SpaceX’s proposal, on April 2, 2021, the contracting officer opened post-selection price negotiations with only SpaceX.⁵² In doing so, it permitted SpaceX to submit a revised proposal, requesting that SpaceX

⁴⁴ See Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al., 2021 CPD ¶ 265, at 4 (Comp. Gen. July 30, 2021); see also Blue Origin Fed’n, LLC v. United States, 157 Fed. Cl. 74, 83 (2021).

⁴⁵ See SOURCE SELECTION STATEMENT, *supra* note 2, at 8; see also Blue Origin Fed’n, LLC, 157 Fed. Cl. at 82.

⁴⁶ See SOURCE SELECTION STATEMENT, *supra* note 2, at 8.

⁴⁷ See *id.*

⁴⁸ See *id.*

⁴⁹ See generally SOURCE SELECTION STATEMENT, *supra* note 2.

⁵⁰ Blue Origin Fed’n, LLC, 157 Fed. Cl. at 85.

⁵¹ SOURCE SELECTION STATEMENT, *supra* note 2, at 8.

⁵² See Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al., 2021 CPD ¶ 265, at 7 (Comp. Gen. July 30, 2021).

adjust its payment phasing to accommodate NASA's funding limitations, as well as incorporate additional FRRs in an attempt to comply with the Option A BAA's FRR requirements that its original proposal failed to meet.⁵³

On April 16, 2021, after reviewing SpaceX's revised proposal, Kathryn L. Lueders—the Source Selection Authority (“SSA”) responsible for making the final contract award decision—announced that she selected SpaceX as the sole contractor to proceed with the HLS mission.⁵⁴ In her Source Selection Statement, Lueders explained:

My selection determination for SpaceX's proposal is based upon the results of its evaluation considered in light of the Agency's currently available and anticipated future funding for the Option A effort. In making my selection, I examine the totality of the SEP's evaluation of SpaceX's proposal across the Option A solicitation's evaluation criteria, as well as the relative weighting of those criteria as stated therein. This analysis leads me to the conclusion that SpaceX's proposal is meritorious and advantageous to the Agency, and that it aligns with the objectives as set forth in this solicitation. Specifically, I conclude that SpaceX's acceptable technical approach coupled with its outstanding management approach provide abundant value for NASA at its Total Evaluated Price. Moreover, as a result of the price negotiations discussed above, the Agency's budget now permits the award of a contract to SpaceX. Therefore, I select SpaceX's proposal for an Option A contract award.⁵⁵

Lueders further explained that it was not in NASA's best interest to engage in post-selection negotiations with the other two competitors, whose proposals she determined did not provide sufficient value to the government.⁵⁶ When explaining the rationale behind declining to engage in negotiations with Blue Origin specifically, Lueders conceded that its proposal had merit but stated that NASA did not have enough funding “to even attempt to negotiate a price from Blue Origin that could potentially enable a contract award.”⁵⁷ This statement that budgetary constraints influenced her decision aligned with the fact that, for the relevant fiscal year, Congress only provided a quarter of what NASA requested for the development of moon landers.⁵⁸

E. Blue Origin's Protests

On April 26, 2021, Blue Origin and Dynetics filed bid protests with the GAO, raising concerns over both NASA's decision to award a single

⁵³ See *id.* at 8–10.

⁵⁴ See generally SOURCE SELECTION STATEMENT, *supra* note 2.

⁵⁵ *Id.* at 13–14.

⁵⁶ See *id.* at 20, 24.

⁵⁷ *Id.* at 20.

⁵⁸ See Kenneth Chang, *Jeff Bezos' Rocket Company Challenges NASA Over SpaceX Moon Lander Deal*, N.Y. TIMES (Apr. 26, 2021), <https://www.nytimes.com/2021/04/26/science/spacex-moon-blue-origin.html> [<https://perma.cc/EM53-99LT>].

contract to SpaceX and its evaluation of the proposals.⁵⁹ Specifically, Blue Origin argued in its protest that NASA deviated from its stated intention to give multiple awards, violated anti-competition premises of procurement law, improperly waived a material solicitation provision for SpaceX, and “conflicted with Broad Agency Announcement (BAA) rules and practices, among other reasons.”⁶⁰

In a statement regarding the protest, Blue Origin officials shared, “In NASA’s own words, it has made a ‘high risk’ selection. Their decision eliminates opportunities for competition, significantly narrows the supply base, and not only delays, but also endangers America’s return to the moon. Because of that, we’ve filed a protest with the GAO.”⁶¹

General Counsel Thomas H. Armstrong, acting on behalf of the GAO, denied the protests on July 30, 2021.⁶² In doing so, Armstrong reasoned that FAR part 35 affords NASA broad discretion, Blue Origin waived some of its arguments, and Blue Origin failed to sufficiently demonstrate standing.⁶³

Despite the GAO denying the protests, Blue Origin did not back down.⁶⁴ On August 11, 2021, Bezos issued a statement saying that the GAO opinion, among other things, confirmed that “there were significant issues with how NASA conducted this procurement process.”⁶⁵ Two days later, on August 13, Blue Origin filed a lawsuit against NASA in the CoFC.⁶⁶ In its complaint, Blue Origin alleged that NASA waived material solicitation safety requirements for SpaceX and conducted unequal discussions, among many other allegations.⁶⁷

While there was much anticipation about how the suit would progress, on November 4, 2021, the CoFC ultimately dismissed Blue Origin’s complaint.⁶⁸ In the memorandum opinion published on November 18, Judge Richard A. Hertling on behalf of the court concluded that Blue Origin lacked standing,

⁵⁹ See *Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al.*, 2021 CPD ¶ 265, at 13–14 (Comp. Gen. July 30, 2021).

⁶⁰ Chelsea Gohd, *Blue Origin and Dynetics File Protests to GAO After SpaceX Wins NASA’s Moon Lander Contract*, SPACE.COM (Apr. 28, 2021), <https://www.space.com/blue-origin-dynetics-protest-nasa-spacex-starship-moon-lander> [<https://perma.cc/J3XY-FNRX>]; see *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265 at 14, 16.

⁶¹ Gohd, *supra* note 60.

⁶² See *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265 at 76.

⁶³ See *id.* at 75–76.

⁶⁴ See *id.* at 76.

⁶⁵ Jeff Foust, *Blue Origin Sues NASA over Human Landing System Contract*, SPACE NEWS (Aug. 16, 2021), <https://spacenews.com/blue-origin-sues-nasa-over-human-landing-system-contract/> [<https://perma.cc/GH23-5AVC>].

⁶⁶ See *id.*

⁶⁷ See *Blue Origin Fed’n, LLC v. United States*, 157 Fed. Cl. 74, 80 (2021).

⁶⁸ See *id.* at 113–114.

waived several of its objections, and failed to demonstrate that the court should interfere with NASA's decision-making.⁶⁹

"Not the decision we wanted, but we respect the court's judgment, and wish full success for NASA and SpaceX on the contract," Bezos wrote in response on Twitter, implying that he would no longer continue litigation.⁷⁰

Although Blue Origin's suits have since subsided, close review of its protests raise questions as to whether the CoFC, along with the GAO, should have allowed conventional procedural barriers to overshadow serious issues in choosing to dismiss the protests.⁷¹

F. Legal Determinations in a Bid Protest

A contractor who wants to challenge the award of a federal contract or the terms of a solicitation for a federal contract can file a bid protest with either the agency, the GAO, or the CoFC.⁷² The GAO is an agency of Congress under the Comptroller General that serves as an independent, impartial forum and is often called the "congressional watchdog."⁷³ It derives its bid protest jurisdiction from the Competition in Contracting Act of 1984 ("CICA"),⁷⁴ and attorneys within the GAO's Procurement Law Control Group possess specific expertise in adjudicating federal government procurement matters.⁷⁵ When a protestor promptly makes a bid protest to the GAO, CICA's automatic stay provision requires the Contracting Officer to refrain from awarding a contract if it has not done so already, or to suspend contract performance while the protest is pending if the contract has already been awarded.⁷⁶

The GAO generally uses a deferential standard of review in evaluating bid protests, considering whether federal agencies have complied with government

⁶⁹ See *id.* at 74–75.

⁷⁰ Jeff Bezos (@JeffBezos), TWITTER (Nov. 4, 2021, 1:23 PM), <https://twitter.com/jeff-bezos/status/1456311095761637384> [<https://perma.cc/7EQ3-4AA9>].

⁷¹ See generally *Blue Origin Fed'n, LLC*, 157 Fed. Cl.; *Blue Origin Fed'n, LLC; Dynetics, Inc.-A Leidos Co.*, B-419783 et al., 2021 CPD ¶ 265 (Comp. Gen. July 30, 2021).

⁷² See *FAQs*, U.S. GOV'T ACCOUNTABILITY OFF., <https://www.gao.gov/legal/bid-protests/faqs> [<https://perma.cc/5CWP-ECJ4>] (last visited Oct. 9, 2022); see also FAR 33.103–.105 (2021).

⁷³ *About*, U.S. GOV'T ACCOUNTABILITY OFF., <https://www.gao.gov/about> [<https://perma.cc/G2TK-73ZZ>] (last visited Oct. 9, 2022).

⁷⁴ See 41 U.S.C. § 253 (2018).

⁷⁵ See U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-510SP, *BID PROTESTS AT GAO: A DESCRIPTIVE GUIDE 5* (2018) [hereinafter GAO-18-510SP]; Michael J. Schaengold et al., *Choice of Forum for Federal Government Contract Bid Protests*, 18 FED. CIR. B.J. 243, 246 (2009).

⁷⁶ See 31 U.S.C. § 3553(d) (2018).

procurement laws and regulations.⁷⁷ If the GAO chooses to sustain the protest, it can recommend a variety of corrective actions as remedies.⁷⁸ For example, it can recommend recompeting the contract, issuing a new solicitation, and awarding bid preparation and bid protest costs.⁷⁹ Although these recommendations are not binding, the failure to follow them will be reported by the GAO to Congress.⁸⁰ As such, agencies generally abide by the GAO’s recommendations to avoid the risk of losing funding from Congress the next year.⁸¹ Alternatively, if the GAO chooses to dismiss the protest, the decision becomes part of the agency record.⁸² Since the GAO is not a court—meaning the rules of preclusion do not apply—a protestor can still file a new suit in the CoFC.⁸³

The CoFC is an Article I court that derives its bid protest jurisdiction from the Tucker Act, 28 U.S.C. § 1491(b)(1).⁸⁴ Judges at the CoFC are not required to have government contracts experience, although many do.⁸⁵ Unlike the GAO, the CoFC does not have an automatic stay provision.⁸⁶ A bid protester can therefore seek a preliminary injunction or a temporary restraining order to stay an award or performance of a contract “so as to preserve the status quo pending the outcome of the litigation.”⁸⁷ The standard of review in the CoFC is governed by the Administrative Procedure Act (“APA”),⁸⁸ which provides *de novo* review of agency determinations on questions of law and deferential review on questions of fact.⁸⁹ This deferential review is known as

⁷⁷ See GAO-18-510SP, *supra* note 75, at 5; JOSHUA SCHWARTZ, CASES AND MATERIALS FOR A SURVEY OF GOVERNMENT PROCUREMENT LAW 5 (2021) (desktop published, on file with author).

⁷⁸ See 31 U.S.C. § 3554 (2018).

⁷⁹ See *id.*

⁸⁰ See SCHWARTZ, *supra* note 77, at 74, 79.

⁸¹ See BEN WILHELM, CONG. RSCH. SERV., IF11807, GAO AND INSPECTOR GENERAL RECOMMENDATIONS TO AGENCIES: AN INTRODUCTION (2021).

⁸² See 31 U.S.C. § 3556 (2018).

⁸³ See *id.*

⁸⁴ 28 U.S.C. § 1491(b)(1) (2018). The statute reads,

[T]he Unite[d] States Court of Federal Claims . . . shall have jurisdiction to render judgment on an action by an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement.

Id.

⁸⁵ See Schaengold et al., *supra* note 75, at 248.

⁸⁶ See SCHWARTZ, *supra* note 77, at 409.

⁸⁷ *Id.*

⁸⁸ 5 U.S.C. §§ 551–559; see SCHWARTZ, *supra* note 77, at 411.

⁸⁹ See 5 U.S.C. § 706 (2018); see also SCHWARTZ, *supra* note 77, at 410.

the arbitrary and capricious standard, in which the CoFC reviews whether an agency's selection was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."⁹⁰ Under the arbitrary and capricious standard, an agency's decision may only be set aside if it lacks a rational basis or involves a violation of regulation or procedure.⁹¹ In other words, a court may not substitute its own judgment for that of the agency simply because it is inclined to reach a different decision.⁹² If the CoFC dismisses the protest, the protestor may appeal its decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit").⁹³

As a threshold matter, a protestor must meet the procedural requirements set forth by a bid protest forum. First, a protestor must comply with timeliness requirements; if they fail to do so, they waive the right to have their arguments heard.⁹⁴ For instance, if a protestor challenges a contract award based upon patent ambiguities or defects—improprieties in the solicitation that were apparent prior to the receipt of initial proposals—their challenge will be waived.⁹⁵

Second, a protestor must have standing.⁹⁶ Neither the GAO or CoFC are Article III courts obligated to impose case or controversy requirements.⁹⁷ As such, the GAO's standing rules are supplied by CICA instead.⁹⁸ Under CICA, a protestor must be an "interested party," defined as "an actual or prospective bidder or offeror whose direct economic interest would be affected by the award of the contract or by failure to award the contract."⁹⁹ On its face, this provision is less restrictive than normal judicial standing tests since any bidder could likely show that its economic fortunes would be affected by whether or not it received a contract.¹⁰⁰ However, a number of GAO bid protest decisions have taken a more restrictive attitude toward standing, indicating that

⁹⁰ 5 U.S.C. § 706(2)(A) (2018).

⁹¹ See SCHWARTZ, *supra* note 77, at 361; see also *Blue Origin Fed'n, LLC v. United States*, 157 Fed. Cl. 74, 104 (2021) (citing *Impresa Construzioni Geom. Domenico Garufi v. United States*, 238 F.3d 1324, 1338 (Fed. Cir. 2001)).

⁹² See SCHWARTZ, *supra* note 77, at 361.

⁹³ See *FAQs: Appeals*, U.S. CT. FED. CL., <http://www.uscfc.uscourts.gov/faqs/> [<https://perma.cc/V9TY-X398>] (last visited Sept. 25, 2022).

⁹⁴ See generally SCHWARTZ, *supra* note 77, at 407; see also *Bid Protests*, U.S. GOV'T ACCOUNTABILITY OFF., <https://www.gao.gov/legal/bid-protests#paragraph-636> [<https://perma.cc/N9Z4-DTJ7>] (last visited Sept. 28, 2022).

⁹⁵ See 4 C.F.R. § 21.2(a)(1) (2021).

⁹⁶ See generally SCHWARTZ, *supra* note 77, at 407–09.

⁹⁷ See *id.* at 408–09.

⁹⁸ See *id.* at 334.

⁹⁹ 31 U.S.C. § 3551(2)(A) (2018).

¹⁰⁰ See SCHWARTZ, *supra* note 77, at 334.

in order to have standing, a protestor must show that it would have a substantial chance of receiving the contract award or a new solicitation but for being prejudiced by the alleged errors.¹⁰¹

Similarly, to establish standing in the CoFC, 28 U.S.C. § 1491(b)(1) states a protestor must be “an interested party.”¹⁰² However, the statute does not define the term “interested party,” leaving unclear whether the CoFC follows the standing principles under the APA or the standing requirements under CICA.¹⁰³ In order to resolve this problem, the Federal Circuit in *American Federation of Government Employees v. United States*¹⁰⁴ construed “interested party” to correspond with the interpretation of the term set forth in CICA.¹⁰⁵ This means that the standing requirement for post-award bid protests in the CoFC is essentially the same as the standing requirement in the GAO:¹⁰⁶ the party must show that it is an actual or prospective bidder who possesses the requisite direct economic interest.¹⁰⁷ Like the GAO standard, to satisfy the “direct economic interest” component, a plaintiff before the CoFC must demonstrate prejudice by showing it had a “substantial chance” of receiving the contract award but for the alleged error it identified in its protest.¹⁰⁸ Under this language, a protestor does not need to prove that it would have received the contract but for the alleged error, but that it was at least within the “zone of active consideration.”¹⁰⁹

This approach to standing might still be evolving, however, as the Federal Circuit recently appeared to take a less restrictive approach to standing in its 2020 decision in *Acetris Health, LLC v. United States*.¹¹⁰ In this case, the court held it was enough for the protestor to show that the same protest issues were likely to arise in other procurements in which it intended to bid in the near future to be considered an interested party.¹¹¹ This decision not only indicates that the CoFC has jurisdiction to hear a bid protest challenge to an agency’s position that could be implicated in future procurements, but also signifies

¹⁰¹ See, e.g., McDonald-Bradley, B-270126, 96-1 CPD ¶ 54, at 3 (Comp. Gen. Feb. 8, 1996).

¹⁰² 28 U.S.C. § 1491(b)(1) (2018).

¹⁰³ See 5 U.S.C. § 702; see also SCHWARTZ, *supra* note 77, at 407–08.

¹⁰⁴ 258 F.3d 1294 (Fed. Cir. 2001).

¹⁰⁵ See *id.* at 1302.

¹⁰⁶ See 31 U.S.C. § 3551(2)(a) (2018).

¹⁰⁷ See, e.g., Rex Serv. Corp. v. United States, 448 F.3d 1305, 1307 (Fed. Cir. 2006).

¹⁰⁸ Info. Tech. & Apps. Corp. v. United States, 316 F.3d 1312, 1319 (Fed. Cir. 2003).

¹⁰⁹ CACI, Inc.-Fed. v. United States, 719 F.2d 1567, 1574–75 (Fed. Cir. 1983) (quoting Morgan Bus. Assocs., Inc. v. United States, 619 F.2d 892, 896 (Ct. Cl. 1980)).

¹¹⁰ 949 F.3d 719 (Fed. Cir. 2020).

¹¹¹ See *id.* at 727–28.

a shift towards viewing protesters as informants of potential wrongdoing rather than mere claimants.¹¹²

II. Analysis: Assessment of Blue Origin's Protests

Within the lengthy opinions by the GAO and the CoFC outlining their reasons for dismissing Blue Origin's protests, it is important to acknowledge that both forums did their due diligence in addressing many of the flaws in Blue Origin's claims.¹¹³ However, there were some strengths in Blue Origin's protests that warranted further assessment but were circumvented through the application of conventional procedural constraints.

A. Flaws in Blue Origin's Protests

Many of the arguments Blue Origin raised were rightfully rejected. For example, in response to Blue Origin's argument that NASA was inconsistent with its announcement's stated preference for multiple awards, the GAO explained that NASA was within their right to only give a single award.¹¹⁴ In explaining so, the GAO stated that "agencies acquiring [new] research and development generally enjoy broad discretion with respect to the number of contract awards to make, consistent with their needs and available funding."¹¹⁵ Additionally, the GAO explained that although the Option A BAA stated an intention for two awards, this intention did not impose a legal obligation on the agency to do so, especially since the express terms of the Option A BAA put the protesters on notice that NASA could make a single award.¹¹⁶

Further, in response to Blue Origin's argument that NASA's decision to award a sole-source contract violated anti-competition premises of procurement law, the GAO explained that NASA was within their right to do so.¹¹⁷ Specifically, Blue Origin argued that NASA's decision to award a contract only to SpaceX would "create a noncompetitive environment for NASA's future HLS requirements," as well as introduce "material long term program risks by relying exclusively on SpaceX."¹¹⁸ This is not the first time a concern over the

¹¹² See Christopher R. Yukins, *Stepping Stones to Reform: Making Agency-Level Bid Protests*, 50 PUB. CONT. L.J. 197, 221 (2021) (citing *Acetris Health, LLC*, 949 F.3d at 727–28).

¹¹³ See generally *Blue Origin Fed'n, LLC v. United States*, 157 Fed. Cl. 74 (2021); *Blue Origin Fed'n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al.*, 2021 CPD ¶ 265 (Comp. Gen. July 30, 2021).

¹¹⁴ See *Blue Origin Fed'n, LLC*, 2021 CPD ¶ 265, at 21–24.

¹¹⁵ *Id.* at 21 (citations omitted).

¹¹⁶ See *id.* at 22–23; see also APPENDIX H BROAD AGENCY ANNOUNCEMENT, *supra* note 21, at 57.

¹¹⁷ See *Blue Origin Fed'n, LLC*, 2021 CPD ¶ 265, at 22–23.

¹¹⁸ *Id.* at 22.

danger of awarding sole-source contracts in the context of space procurement has been raised—ironically, similar concerns over competition were raised by SpaceX itself in the past when it was in the position of a bid protestor, challenging the award of a single-source Evolved Expendable Launch Vehicle (“EELV”) contract to United Launch Alliance (“ULA”).¹¹⁹ Nonetheless, the GAO explained that Blue Origin’s concerns did not demonstrate an actual violation of procurement law, despite the fact that they presented “significant acquisition policy and public policy questions.”¹²⁰

B. Strengths in Blue Origin’s Protests

Despite the flaws highlighted above, Blue Origin raised some legally and factually sound arguments that fell within the jurisdiction of both bid protest forums. For example, the GAO agreed with Blue Origin that NASA improperly waived a material solicitation provision for SpaceX.¹²¹ Specifically, the GAO found that SpaceX’s proposal failed to include mandatory FRRs for each launch contemplated by its proposed concept of operations as required by the Option A BAA.¹²² Although NASA argued that “the solicitation was ambiguous as to whether an FRR was required for each launch, or for the launch of each type of element,” the GAO rejected this and stated that an FRR was required to be completed before each launch of an HLS element—which includes the supporting spacecraft—and thus even SpaceX’s three proposed FRRs were insufficient since its concept of operations necessitated sixteen launches.¹²³

Additionally, the proceeding CoFC opinion noted that NASA deviated from typical BAA procedures under FAR 35.016 further than it originally stated.¹²⁴ Specifically, not only was there a common work statement, but NASA did, in fact, compare the proposals to each other during parts of the evaluation:

NASA’s comparison among proposals is evidenced by the SSA’s Source Selection Statement. The SSA acknowledged the competitive nature of the acquisition by explaining that ‘NASA’s HLS acquisition strategy has been to maintain a competitive environment through the initial crewed lunar demonstrations and beyond, thereby creating performance and pricing incentives for contractors at all stages of the HLS

¹¹⁹ See *Space Expl. Techs. Corp. v. United States*, 116 Fed. Cl. 68, 69, 71 (2014) (issuing a preliminary injunction suspending the contract award to ULA); see also Alexander Rogosa, *Shifting Spaces: The Success of the SpaceX Lawsuit and the Danger of Single-Source Contracts in America’s Space Program*, 25 FED. CIR. B.J. 101, 102, 118 (2015).

¹²⁰ *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265, at 22–23.

¹²¹ See *id.* at 71–73.

¹²² See *id.* at 73.

¹²³ *Id.* at 71–73.

¹²⁴ See *Blue Origin Fed’n, LLC v. United States*, 157 Fed. Cl. 74, 90 (2021).

Program.’ Moreover, her summary of evaluation results placed the technical and management adjectival ratings for all offerors in a common chart and then explicitly compared proposal prices.¹²⁵

This finding could be relatively important given that, if NASA’s solicitation was deemed to be more like a competitive proposal conducted pursuant to FAR part 15 rather than a BAA pursuant to FAR part 35, it would have been required to conduct discussions with all offerors remaining in the competition instead of engaging in post-selection negotiations only with SpaceX.¹²⁶ Thus, while an agency conducting post-selection negotiations in a BAA procurement is “generally under ‘no obligation to follow the specific requirements for discussions set forth in FAR part 15,’” this raises the question of whether a different provision of the FAR should govern the procurement when NASA applies different procedures from those set forth in its solicitation.¹²⁷ Further, while both forums indicated NASA is afforded significant discretion when conducting BAA procurements, the question remains unaddressed as to whether a different level of deference should apply when NASA deviates from its stated procurement procedures.¹²⁸

C. Procedural Barriers Invoked

While Blue Origin’s protests had many strengths, they were overshadowed by procedural barriers—specifically, timeliness and standing issues.

1. Timeliness Issues

In regard to timeliness issues, the GAO stated that even if it were to conclude that FAR part 15 principles should have applied in this procurement instead of FAR part 35, the strict rules for the timely submission of protests under 4 C.F.R. § 21.2(a)(1) would render Blue Origin’s objections to the Option A BAA’s terms patently untimely anyway.¹²⁹

Similarly, the CoFC held that Blue Origin had waived many of its arguments on the basis that it should have been aware of those arguments before

¹²⁵ *Id.* (citation omitted).

¹²⁶ See FAR 15.306(d)(1) (2021) (“[D]iscussions . . . must be conducted by the contracting officer with each offeror within the competitive range.”).

¹²⁷ Blue Origin Fed’n, LLC; Dynetics, Inc.-A Leidos Co., B-419783 et al., 2021 CPD ¶ 265, at 28 (Comp. Gen. July 30, 2021) (quoting Spaltudaq Corp., B-400650 et. al, 2009 CPD ¶ 1, at 5 (Comp. Gen. Jan. 6, 2009)).

¹²⁸ See *id.* at 32 (citations omitted); see also *Blue Origin Fed’n, LLC*, 157 Fed. Cl. at 90.

¹²⁹ See *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265, at 30; see also 4 C.F.R. § 21.2(a)(1) (2021) (“Protests based upon alleged improprieties in a solicitation which are apparent prior to bid opening or the time set for receipt of initial proposals shall be filed prior to bid opening or the time set for receipt of initial proposals.”).

the contract was awarded and protested them at that time.¹³⁰ For instance, despite the fact that the government and SpaceX’s interpretation of the term “HLS element” directly conflicted with the SOW’s own definition of that term, the CoFC concluded that SpaceX’s interpretation was reasonable in addition to concluding that Blue Origin’s interpretation, which was sustained by the GAO, was also reasonable.¹³¹ As a result, the judge concluded the term was patently ambiguous—an obvious discrepancy that “could have been discovered by reasonable and customary care.”¹³² In categorizing the term as such, the court stated that Blue Origin should have known that the SOW’s term had more than one reasonable meaning—and in turn, should have raised the issue earlier—but since it did not, its challenge was waived.¹³³

2. *Standing Issues*

In regard to standing issues, the GAO stated there was “no basis on which to sustain the protests because the protesters have failed to establish any reasonable possibility of resulting competitive prejudice” for the purpose of determining standing.¹³⁴ In defining prejudice, the GAO said, “Competitive prejudice from such a waiver of solicitation requirements exists only where (i) the requirement was not similarly waived for the protester, or (ii) where the protester would have been able to alter its proposal to its competitive advantage if given the opportunity to respond to the relaxed term.”¹³⁵ SpaceX’s concept of operations was considerably different from Blue Origin’s, with Blue Origin only needing FRRs for its three proposed launches versus SpaceX’s sixteen proposed launches.¹³⁶ As such, since Blue Origin’s proposal did not fail to include the requisite FRRs for its own concept of operations, the GAO found that “Blue Origin [could not] reasonably establish how it could have improved the competitiveness of its proposal had it known that the agency would relax the FRR requirement as it did.”¹³⁷

Similarly, in the CoFC, the judge held that issues with Blue Origin’s own bid prevented it from establishing prejudice, despite any potential flaws in SpaceX’s bid.¹³⁸ For instance, the opinion stated that Blue Origin did not have a substantial chance of award because its milestone payments were insurmountably farther outside of NASA’s available budget than SpaceX’s

¹³⁰ See generally *Blue Origin Fed’n, LLC*, 157 Fed. Cl. at 95–105.

¹³¹ See *id.* at 98; *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265, at 72–73.

¹³² *Blue Origin Fed’n, LLC*, 157 Fed. Cl. at 98 (citations omitted).

¹³³ See *id.* at 99; see also discussion *infra* Section II.C.3.

¹³⁴ *Blue Origin Fed’n, LLC*, 2021 CPD ¶ 265, at 73.

¹³⁵ *Id.*

¹³⁶ See *id.* at 74.

¹³⁷ *Id.*

¹³⁸ See *Blue Origin Fed’n, LLC*, 157 Fed. Cl. at 90–91.

milestone payments were.¹³⁹ Specifically, Blue Origin's proposed payments for the 2021 fiscal year would have been "more than triple" the \$345 million budget NASA had available for the contract.¹⁴⁰

However, if, for example, Blue Origin was able to show that *both* bids were unworkable—its bid was more expensive, but SpaceX's had greater technical flaws—then perhaps Blue Origin would have stood a higher chance of receiving a portion of the budget in a later contract award after NASA reviewed its requirements in light of its budget. This would be of relevance since Blue Origin claimed in its open letter to NASA that it could bridge the budgetary shortfall by waiving all payments over two fiscal years up to \$2 billion and accepting a firm fixed-price contract for all of its work, among other offers.¹⁴¹

3. *Identifiable Inconsistencies*

The rationales provided by both forums for rejecting Blue Origin's protests conflict with the very premise of the BAA itself. For instance, the rationale by the GAO expects Blue Origin to demonstrate a comparison of the competitiveness of its proposal, even when there was not supposed to be a comparison of proposals due to their uniqueness under BAA procedures.¹⁴² Similarly, the rationale by the CoFC expects Blue Origin to anticipate not only that a definition that conflicts with the SOW's very own definition could be considered reasonable, but also that a certain term would end up being of significance for a competitor's design completely different than its own.¹⁴³ These expectations are relatively impossible for Blue Origin to meet given the complexity of custom-designed space systems, where there is no way for a bidder to anticipate the scientific and engineering limitations of its competitor's designs that have yet to be developed.

Nonetheless, neither forum took these inconsistencies with the BAA into account—nor the previously mentioned discrepancies—due to the restraining nature of the procedural barriers invoked and the unwavering deference that both forums afforded NASA in its decision-making. This determination is not surprising from either of these forums given the relatively low success rate of contract protests, especially due to standing and timing issues.¹⁴⁴ However,

¹³⁹ See *id.* at 91.

¹⁴⁰ *Id.* at 90–91.

¹⁴¹ See *id.* at 91; see also Jeff Bezos, *Open Letter to Administrator Nelson*, BLUE ORIGIN: BLOG (July 26, 2021), <https://www.blueorigin.com/news/open-letter-to-administrator-nelson> [<https://perma.cc/EBM9-5T7M>].

¹⁴² See *Blue Origin Fed'n, LLC*, 157 Fed. Cl. at 90.

¹⁴³ See *id.* at 98.

¹⁴⁴ See generally *Another One Bites the Dust: COFC Dismisses Protest for Lack of Standing Based on OCI Issue Not Raised Prior to Litigation*, MILLER & CHEVALIER: LITIGATION ALERT (Jan. 27, 2022), <https://www.millerchevalier.com/publication/>

this should not always be the case—especially for protests that raise lingering safety concerns such as the one at hand.

D. Lingering Safety Concerns

Since its inception, NASA has experienced repeated failures of management to effectively assess the safety risks inherent in its space technology. One of the most memorable instances in history is the space shuttle Challenger disaster of 1986, when the shuttle exploded shortly after liftoff and killed all seven crew members onboard.¹⁴⁵ The explosion ensued after the O-ring, “a tiny rubber part . . . which formed the seal between sections of the solid rocket boosters,” was too cold to expand properly, allowing a leak in the booster.¹⁴⁶ In the months following the explosion, a Presidential Commission led by former Secretary of State William P. Rogers “ultimately flagged the root cause of the accident as ‘a serious flaw in the decision-making process leading up to the launch.’”¹⁴⁷ In its report, the Commission noted that despite information available to NASA and Morton Thiokol—the contractor that built the solid rocket boosters for NASA’s Challenger mission—about the temperature sensitivity of O-rings, the concern remained absent from all the flight-readiness documents.¹⁴⁸ Even on the morning of the disaster, the agency was made aware that the temperature on the launch pad was too cold for the O-ring to work properly, yet it still deemed the launch appropriate.¹⁴⁹ A follow-up report based on personal observations on the reliability of the shuttle disclosed that NASA official management would relax the strictness of certification criteria used in FRRs so that flights could be certified in time, therefore flying in a relatively unsafe condition.¹⁵⁰ The report also disclosed that NASA official management believed the probability of failure to be far

another-one-bites-dust-cofc-dismisses-protest-lack-standing-based-oci-issue-not-raised [https://perma.cc/B9H8-ZKM5].

¹⁴⁵ See *The Space Shuttle Challenger Explodes After Liftoff*, HISTORY: THIS DAY IN HISTORY (Jan. 25, 2022), <https://www.history.com/this-day-in-history/challenger-explodes> [https://perma.cc/NZB2-BGSU].

¹⁴⁶ Amy Shira Teitel, *What Caused the Challenger Disaster*, HISTORY (last updated Jan. 28, 2022), <https://www.history.com/news/how-the-challenger-disaster-changed-nasa> [https://perma.cc/AV6S-QMSK].

¹⁴⁷ *Id.*; see NAT’L AERONAUTICS & SPACE ADMIN., *Report to the President by the Presidential Commission on the Space Shuttle Challenger Accident* 104 (1986), https://sma.nasa.gov/SignificantIncidents/assets/rogers_commission_report.pdf [https://perma.cc/9F85-WLH4].

¹⁴⁸ See Teitel, *supra* note 146.

¹⁴⁹ See *id.*

¹⁵⁰ See RICHARD P. FEYNMAN, APPENDIX F: PERSONAL OBSERVATIONS ON RELIABILITY OF SHUTTLE 1, 11 (1986), <https://www.refsmmat.com/files/reflections.pdf> [https://perma.cc/V785-UUC4].

less than many of the engineers did, either in an attempt to assure the government of NASA's success in order to keep receiving funds or because of a drastic lack of communication between the managers and their engineers.¹⁵¹

Similarly, in 2003, seven astronauts died as the space shuttle Columbia broke up while entering the atmosphere over Texas.¹⁵² According to a report by the Columbia Accident Investigation Board that strongly criticized NASA's safety culture, "[b]y the eve of the *Columbia* accident, institutional practices that were in effect at the time of the *Challenger* accident—such as inadequate concern over deviations from expected performance, a silent safety program, and schedule pressure—had returned to NASA."¹⁵³

Unsurprisingly, NASA has recently faced numerous challenges in the early execution of its Artemis Mission. For example, NASA was forced to cancel its most recent SLS launch attempts scheduled for August 29, 2022, and September 3, 2022, after unresolved leaks in the shuttle raised potential flammability hazards.¹⁵⁴ Despite the availability of more easily controllable fuel alternatives—and NASA already experiencing similar struggles with hydrogen leaks in space shuttles between 1981 and 2011—NASA officials still elected to use liquid hydrogen as fuel for the rocket.¹⁵⁵

NASA's decision-making capabilities to adequately assess risks remain in doubt with the rescheduled SLS launch.¹⁵⁶ On September 9, 2022, the GAO issued a report criticizing NASA for its continued use of insufficient schedule management guidance in the execution of its Artemis Plan.¹⁵⁷ Among other recommendations, the GAO stated that "NASA will need to ensure that the

¹⁵¹ See *id.* at 11.

¹⁵² See *Columbia Space Shuttle Mission Ends in Disaster*, HISTORY (Jan. 29, 2021), <https://www.history.com/this-day-in-history/columbia-mission-ends-in-disaster> [<https://perma.cc/CY7K-TRZC>].

¹⁵³ NAT'L AERONAUTICS & SPACE ADMIN., COLUMBIA ACCIDENT INVESTIGATION BOARD REPORT 101 (2003), http://s3.amazonaws.com/akamai.netstorage/anon.nasa-global/CAIB/CAIB_lowres_full.pdf [<https://perma.cc/HGS9-RGST>].

¹⁵⁴ See Alexandra Witze, *Why NASA's Artemis Moon Launch Is Delayed — and What's Next*, NATURE (Sept. 8, 2022), <https://www.nature.com/articles/d41586-022-02867-6> [<https://perma.cc/9DM8-8AR3>].

¹⁵⁵ See *id.*

¹⁵⁶ The SLS launch is scheduled to occur on November 16, 2022. See *NASA SLS LAUNCH*, KENNEDY SPACE CENTER, <https://www.kennedyspacecenter.com/launches-and-events/events-calendar/2022/november/rocket-launch-nasa-sls-artemis-i> [<https://perma.cc/3DZG-2TJ2>] (last visited Nov. 14, 2022). This Note was written and sent to publication before the scheduled launch date.

¹⁵⁷ See generally U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-105323, NASA LUNAR PROGRAMS: IMPROVED MISSION GUIDANCE NEEDED AS ARTEMIS COMPLEXITY GROWS (2022) [[hereinafter](#) GAO-22-105323].

lunar programs, once in operation, will be safe for the crew and can operate in a challenging deep space environment,” and that “additional steps [are] needed to ensure that senior NASA leaders have quality, risk-informed information for decision-making.”¹⁵⁸

Given NASA’s tendency to alter certification criteria used in FRRs and to underestimate the probability of a failure resulting in loss of vehicle and loss of human life, the success of the HLS launch and other future missions still remain a significant area of concern—one left unchecked by both bid protest forums in their dismissals of Blue Origin’s complaints. As such, it is time for bid protest forums to start allowing significant safety concerns to play a heavier role in the determination of bid protests.

III. Solution: Enabling Exceptions to Traditional Procedural Barriers for Significant Space Procurement Issues

Moving forward, bid protest authorities should avoid applying traditional procedural requirements that could discourage, rather than encourage, future competitors from bringing protests in cases that implicate important safety concerns. Instead, they should push forward a new wave of precedent in the evolution of bid protest issues by granting unique exceptions to timing and standing constraints when safety is at issue.

A. Timeliness Exceptions

At the forefront, the GAO timeliness rule (4 C.F.R. § 21.2(a)(1)) is not binding on other forums under the Federal Circuit’s jurisdiction such as the CoFC.¹⁵⁹ The CoFC found as such in *Software Testing Solutions, Inc. v. United States*,¹⁶⁰ in which the defendant argued that the plaintiff’s protest should be subjected to the GAO’s timeliness requirement because several past decisions had applied this requirement.¹⁶¹ In recognizing that there may be different ways to interpret the past opinions, the CoFC held that “a GAO rule that self-limits that agency’s advisory role [does not] constitute[] a limit, either legally or prudentially, on this court’s exercise of jurisdiction.”¹⁶² Not only is this timeliness rule not binding on other forums, but it is not even binding on the GAO itself according to the plain text of the rule.¹⁶³ Specifically,

¹⁵⁸ *Id.* at 2, 31; see discussion *supra* Section II.C.1.

¹⁵⁹ See 4 C.F.R. § 21.2(a)(1) (2021).

¹⁶⁰ 58 Fed. Cl. 533, 535–36 (2003).

¹⁶¹ See *id.* at 535 (first citing *ABF Freight Sys., Inc. v. United States*, 55 Fed. Cl. 392, 399 (2003) (quoting *N.C. Div. of Servs. for Blind v. United States*, 53 Fed. Cl. 147, 165 (2002)); and then citing *EDP Enters., Inc. v. United States*, 56 Fed. Cl. 498, 500 (2003)).

¹⁶² *Id.* at 535.

¹⁶³ See *id.*; see also *Transatlantic Lines LLC v. United States*, 68 Fed. Cl. 48, 52 (2005).

4 C.F.R. § 21.2(c) provides the exception that the “GAO, for good cause shown, or where it determines that a protest raises issues significant to the procurement system, may consider an untimely protest.”¹⁶⁴ This leaves open the possibility that Blue Origin’s protest, if determined by either forum to have raised a significant issue, could have circumvented any of the aforementioned timeliness issues.

With this in mind, future bid protest officials should endeavor to carve out timeliness exceptions for significant issues, whether that be in their own discretion or explicitly by regulation, such as the exception set forth in 4 C.F.R. § 21.2(c).¹⁶⁵ If the latter, whether the exception is invoked will depend upon the bid protest official’s determination of what may constitute a “significant issue.” Procurements for highly technical developments that concern critical safety—and potential loss of human life—should be encompassed within the bounds of a significant issue designation. NASA’s HLS procurement clearly implicates a significant safety issue, as NASA itself claimed that “the landing on the moon . . . will be the most dangerous and complex flying task attempted by humans in more than 50 years.”¹⁶⁶

Admittedly, encouraging bid protest officials to utilize this exception may raise the slippery-slope concern that some officials may deem too many matters as “significant issues.” However, this concern is checked by prior clarifications to the exception. Specifically, past GAO opinions have dictated that the significant issue exception may be invoked only if the forum believes that consideration of the protest would be “in the interest of the procurement system.”¹⁶⁷ This requirement distinguishes issues that may be of importance to the procurement community as a whole from issues that are merely of importance to the protester in a single procurement.¹⁶⁸

For example, in *Golden North Van Lines, Inc.*,¹⁶⁹ the plaintiff’s protest, which claimed that the solicitation failed to inform bidders of whether option prices would be evaluated, was found to be untimely under 4 C.F.R. § 21.2(a)(1).¹⁷⁰ However, the presiding counsel invoked the timing exception because he

¹⁶⁴ 4 C.F.R. § 21.2(c) (2021).

¹⁶⁵ See *id.*

¹⁶⁶ Release 20-048, *supra* note 23; NASA, *Artemis Announcement: NASA Selects Human Landing Systems*, YouTube (April 30, 2020), <https://www.youtube.com/watch?v=dlHJAKIaALg&t=14s> [<https://perma.cc/C6GP-ZNW7>].

¹⁶⁷ The Dep’t of the Navy; Fairchild Weston Sys., Inc., B-230013, 88-2 CPD ¶ 100, at 1 (Comp. Gen. July 29, 1988).

¹⁶⁸ See, e.g., Carlisle Tire & Rubber Co., B-235413, 89-2 CPD ¶ 152, at 3 (Comp. Gen. Aug. 18, 1989).

¹⁶⁹ B-238874, 90-2 CPD ¶ 44 (Comp. Gen. July 17, 1990).

¹⁷⁰ See *id.* at 2.

believed it was important to clarify the principles that govern when an agency fails to specify whether option prices will be evaluated.¹⁷¹

If the counsel in *Golden* was able to justify invoking the timing exception, the bid protest authorities in Blue Origin’s protests similarly could have justified invoking the timing exception.¹⁷² Specifically, they could have allowed Blue Origin’s protests to be further considered in order to clarify the principles governing BAA procurements, especially those used for the procurement of space technology implicating critical safety issues. The importance of this clarification extends beyond Blue Origin’s individual interests in this single procurement given that similar issues are likely to keep arising in future procurements due to both the magnitude of the inherent risks involved in space technology, as well as the frequent failure of NASA’s management to effectively assess those risks.¹⁷³

B. Standing Exceptions

While both bid protest authorities in Blue Origin’s case elected to apply typical restrictive standing rules, they were not obligated to do so.¹⁷⁴ Bid protest authorities at both the GAO and CoFC are not bound by their own prior decisions nor each other’s decisions.¹⁷⁵ By focusing on whether Blue Origin had a substantial chance of receiving the contract award as the rationale for lacking the requisite prejudice needed to have standing, both forums undermined the significance of Blue Origin’s role as an informer of important issues. Given the vast likelihood that similar safety issues will continue to arise in the context of space procurements,¹⁷⁶ Blue Origin should have been afforded the opportunity to qualify for standing under the relaxed requirements set forth in *Acetris Health*.¹⁷⁷ Moving forward, future bid protest authorities should endeavor to liberalize standing requirements for protestors who raise significant issues surrounding innovative procurements. Allowing potential informants to have standing is especially important given the observations of NASA officials gradually decreasing the strictness of the certification criteria used in FRRs over time, as well as believing probabilities of failure to be substantially lower than what engineers themselves believe.¹⁷⁸

¹⁷¹ See *id.*

¹⁷² See *id.*

¹⁷³ See FEYNMAN, *supra* note 150, at 11.

¹⁷⁴ See Rogosa, *supra* note 119, at 112.

¹⁷⁵ See Schaengold et al., *supra* note 75, at 252–53.

¹⁷⁶ See discussion *supra* Section II.D.; see also GAO-22-105323, *supra* note 157.

¹⁷⁷ See *Acetris Health, LLC v. United States*, 949 F.3d. 719, 727–28 (Fed. Cir. 2020).

¹⁷⁸ See FEYNMAN, *supra* note 150, at 1.

Certainly, any influx of further litigation fostered by this proposed flexibility in standing would not be favorable to an agency's schedule. Blue Origin's protest itself already delayed NASA's mission until at least 2025, since SpaceX had to wait for its resolution before resuming any work on the landing system.¹⁷⁹ However, given the gravity of the matter at hand, it is important for bid protest forums—whether it be the GAO, the CoFC, or the Federal Circuit—to send the message that they will consider important safety allegations to prevent potential instances of failure, instead of relying solely on NASA's "expertise" that continues to diminish with the influx of innovation by the private sector.¹⁸⁰ If this message is effectively conveyed, procedural exceptions to address safety concerns could even put agencies and future bidders on notice to take extra steps in assuring compliance with safety requirements if they want to avoid any unwanted litigation—and any technological failures in the future.

C. Supplemental Suggestions

Ideally, the most concrete method of remedying the issue at hand would be to affirmatively amend regulatory and statutory language to add explicit exceptions or rules for BAA procurements concerning safety related issues. This would eliminate any potential hesitation by judges who are reluctant to carve out exceptions within their own discretion. However, such fraught changes involve lengthy, time-consuming processes.¹⁸¹ In the meantime, space

¹⁷⁹ See Eric M. Johnson, *NASA Tells SpaceX to Halt Lunar Lander Work Pending Contract Challenges*, REUTERS (Apr. 30, 2021, 8:32 PM), <https://www.reuters.com/lifestyle/science/nasa-tells-spacex-halt-lunar-lander-work-pending-challenges-by-rivals-2021-04-30/> [<https://perma.cc/ZCL2-WVFX>]; see also *NASA Outlines Challenges, Progress for Artemis Moon Missions*, Release 21-151, NAT'L AERONAUTICS & SPACE ADMIN. (Nov. 9, 2021), <https://www.nasa.gov/press-release/nasa-outlines-challenges-progress-for-artemis-moon-missions> [<https://perma.cc/LG84-B3B4>]; Bill Chappell, *NASA Says It Can't Put the First Person of Color on the Moon Until at Least 2025*, NAT'L PUB. RADIO (Nov. 10, 2021, 9:59 AM), <https://www.npr.org/2021/11/10/1054232469/nasa-moon-mission-lunar-artemis-2025> [<https://perma.cc/YU89-EVMA>].

¹⁸⁰ See Davenport, *supra* note 1; see also Miriam Kramer, *NASA's Future Is in Private Space Companies' Hands*, AXIOS (Dec. 7, 2021), <https://www.axios.com/nasa-private-spaceflight-plans-5a5710e6-5223-4da3-8c5d-5a712e1d862e.html> [<https://perma.cc/4TY7-SXGG>]; Professor Schooner Contributes to National Academies Study on SmallSat Space Technology, GW LAW: NEWS STORIES (Mar. 28, 2022), <https://www.law.gwu.edu/professor-schooner-contributes-national-academies-study-smallsat-space-technology> [<https://perma.cc/NM5P-5LS4>] (Steven Schooner, GW Law Professor, stating, "The government doesn't control, or have a monopoly over, the new ideas, new tech, production, or means.").

¹⁸¹ See generally H.R. DOC. NO. 110-49, at 35 (2007); OFF. OF THE FED. REG., *A Guide to the Rulemaking Process* (2011).

exploration is not stopping. Short of an amended regulation, or in the interim, it is still up to protestors to point out significant safety issues that agencies like NASA fail to address—and up to bid protest authorities to actually listen.

Conclusion

Despite its dismissal in both the GAO and the CoFC, Blue Origin’s protests not only raised important safety issues with NASA’s HLS procurement process that remain unaddressed, but inadvertently demonstrated the paradox of applying conventional procedural barriers to unconventional space procurement matters. The stringency of timeliness and standing requirements can ultimately be a matter of discretion in the hands of the presiding officials and judges at available bid protest forums. In light of the safety concerns raised in BAA procurements and NASA’s declining expertise in space innovation, future officials should carve out exceptions to timing and standing requirements in order to encourage input from the new wave of space expertise—the commercial companies themselves.

Enforcing the Forced Labor Prohibition: Increasing Transparency and Mandating Supply Chain Due Diligence

Shanni Alon*

Introduction

Modern slavery victimizes more than forty million people around the world.¹ The term “modern slavery” includes state-imposed and private forced labor, sexual exploitation, indentured child labor, and forced marriage.² The United States has abolished formal slavery, yet U.S. enforcement of its laws promulgates modern slavery. To combat forced labor and protect domestic industries, the United States enacted a prohibition on forced labor: Section 307 of the Tariff Act of 1930 (“Section 307”).³ Section 307 aims to reduce, and ultimately eliminate, forced labor for altruistic reasons and to protect domestic industries that would be undercut by slave labor.⁴

U.S. Customs and Border Protection (“CBP”) has historically enforced Section 307 by detaining or seizing imports at U.S. ports of entry when it suspects or finds forced labor in the supply chain, thereby discouraging companies importing their goods into the United States from using forced labor.⁵ Enforcement, however, has been inconsistent.⁶ In the 1980s and 1990s, CBP used its authority under Section 307 to detain goods; however, between 2000 and 2015, CBP no longer instructed ports to detain merchandise.⁷

* J.D., May 2023, The George Washington University Law School; B.A., 2018, The George Washington University. Thank you to my friends and family who are probably very excited to never hear me talk about Section 307 again. This Note is dedicated to my family and friends who have endlessly supported and encouraged me throughout law school.

¹ See *International Day for the Abolition of Slavery, 2 December*, UNITED NATIONS, <https://www.un.org/en/observances/slavery-abolition-day> [<https://perma.cc/4ZLE-D54H>] (last visited Jan. 28, 2022).

² See *id.*

³ See 19 U.S.C. § 1307 (2018).

⁴ See CATHLEEN D. CIMINO-ISAACS ET AL., CONG. RSCH. SERV., R46631, SECTION 307 AND U.S. IMPORTS OF PRODUCTS OF FORCED LABOR: OVERVIEW AND ISSUES FOR CONGRESS 3–4 (2021).

⁵ See *id.* at 3–4, 8–9.

⁶ See *id.* at 5.

⁷ See *id.* at 5–6.

In the years since, there has been a renewed focus on the presence of forced labor in supply chains. During the Obama Administration, Congress strengthened Section 307 by removing the consumptive demand exception, which had allowed merchandise connected to forced labor to be imported if U.S. demand exceeded domestic production, thereby increasing CBP's enforcement of Section 307.⁸ The Trump Administration used Section 307 to target unfair trade practices—particularly focused on China.⁹ More recently during the Biden Administration, Congress enacted a presumption that goods made in China's Xinjiang Uyghur Autonomous Region are the product of forced labor and are thus barred from entry into the United States.¹⁰

However, effective enforcement of Section 307 requires consistency, and the United States fails in this regard. Although CBP has recently increased its enforcement of Section 307, importers have been left with vague pronouncements that their merchandise is being held and have little recourse.¹¹ CBP's instructions provided through official regulations, unofficial tips, and its final decisions lack clarity.¹² This unclear guidance makes it difficult for an importer to prove its merchandise's supply chain does not contain any evidence of forced labor.¹³ Furthermore, this lack of transparency weakens all processes through which the United States, through its various agencies, combats forced labor.¹⁴ Thus, to eliminate forced labor, U.S. enforcement must be effective and consistent. Section 307's forced labor prohibition, if adequately enforced, could disincentivize companies from profiting off the use of forced labor.¹⁵ Ultimately, opaque enforcement weakens Section 307 and fails to protect fair labor standards.

This Note calls attention to the opaque and ineffective enforcement of Section 307, which creates challenges for importers when contesting CBP's processes and ultimately defeats the purpose of the forced labor prohibition

⁸ See *id.* at 1, 6–7.

⁹ See Claire E. Reade & Samuel Witten, *Understanding the US Ban on Importing Forced Labor Goods*, ARNOLD & PORTER (Apr. 17, 2017), <https://www.arnoldporter.com/en/perspectives/publications/2017/04/understanding-the-us-ban-on-importing> [<https://perma.cc/H55S-FGUP>].

¹⁰ See Uyghur Forced Labor Prevention Act, Pub. L. 117-78 § 3, 135 Stat. 1525–32 (2021).

¹¹ See U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-259, FORCED LABOR: CBP SHOULD IMPROVE COMMUNICATION TO STRENGTHEN TRADE ENFORCEMENT 33–34 (2021) (describing CBP's recent attempts to improve enforcement and recommending further improvements) [hereinafter GAO-21-259].

¹² See discussion *infra* Sections II.A.2–3.

¹³ See discussion *infra* Part II.

¹⁴ See discussion *infra* Section II.A.

¹⁵ See generally CIMINO-ISAACS ET AL., *supra* note 4.

because importers are not incentivized to comply with the prohibition due to the unclear nature of CBP's enforcement. This Note offers a solution to clarify how importers can effectively challenge CBP's enforcement mechanisms. CBP provides minimal guidance and leaves importers with little remedy.¹⁶ This confusion limits importers' ability to comply with Section 307 and further hinders other federal agencies' ability to combat forced labor.¹⁷ To solve these deficiencies, this Note proposes that the Federal Circuit acknowledge the existing inefficiencies in CBP's processes and adopt a clear and convincing standard of proof that importers must demonstrate to show lack of forced labor in their supply chains.¹⁸ Additionally, this Note argues that CBP should amend its guidance to increase transparency and recommends Congress enact due diligence legislation.¹⁹

Part I of this Note presents the historical context of the forced labor prohibition, beginning with the implementation of tariffs generally, the prohibition's development, and the progression of enforcement mechanisms. It then outlines importers' ability to challenge CBP's enforcement of Section 307 and highlights the difficulties in doing so. Part II dissects challenges importers face and explores current litigation in which an importer is contesting CBP's refusal to admit its merchandise into the United States. This Note then analyzes whether and how importers might overcome a presumption of forced labor, contextualized with recent legislation that presumes forced labor exists in products from China's Xinjiang region. Part II next discusses the European Union's proposed due diligence law which creates mandatory obligations for companies to protect human rights, which could benefit U.S. importers in their challenges against CBP. Finally, Part III proposes executive, judicial, and legislative solutions to mitigate an importer's difficulty in challenging CBP to promote effective enforcement of Section 307.

I. Background

Since the abolishment of formal slavery, activists in the United States have lobbied for greater emphasis on prohibiting forced labor.²⁰ The forced labor prohibition was suggested as part of the Tariff Act of 1930.²¹ The ban on forced labor, which has been codified as Section 307, bars imports from entry into U.S. ports where there is suspicion that the goods were produced using

¹⁶ See discussion *infra* Section II.A.

¹⁷ See *id.*

¹⁸ See discussion *infra* Section III.A.

¹⁹ See discussion *infra* Sections III.B–C.

²⁰ See CIMINO-ISAACS ET AL., *supra* note 4, at 3.

²¹ See generally 19 U.S.C. ch. 4 (2018).

forced labor.²² Originally, there was a consumptive demand exception, which allowed goods produced using forced labor to be imported in cases where U.S. domestic production of the relevant goods could not meet demand.²³ Enforcement of Section 307 has improved since this exception was removed.²⁴ Nonetheless, the United States has been inconsistent in enforcing fair labor standards and has increasingly used Section 307 as a political tool.²⁵ This part of the Note first analyzes the development of the forced labor prohibition in the United States and then explores how its enforcement has evolved. Understanding the historical context of Section 307 and CBP's enforcement mechanisms is necessary to understand the challenges importers face when protesting CBP's decisions to seize or detain merchandise at U.S. ports.

A. The Tariff Act of 1930

Discussion about the Tariff Act of 1930 first arose during Herbert Hoover's presidential campaign, when he promised to revise tariffs to support struggling domestic farmers.²⁶ Once elected in 1929, he called on Congress to consider the issue of tariffs to address the depressed farm economy.²⁷ Hoover initially proposed a "limited revision" of the tariff on agricultural imports to improve slumped farm prices and increase the cost of imports but ultimately left the matter to Congress.²⁸ Republicans, who at the time promoted protectionist policies, were emboldened by Hoover's distance from the tariff negotiations, and they, along with other non-farm economic interests, lobbied Republican Senator Reed Smoot, chair of the Senate Finance Committee, to increase tariffs.²⁹ In the House, Willis Hawley, a Republican congressman who led the House Ways and Means Committee, ignored the agricultural issue and instead seized the opportunity to raise industrial tariffs.³⁰ Following a fifteen-month debate, Hoover signed the tariff increases into law on June 17,

²² See 19 U.S.C. § 1307 (2018).

²³ See Donna L. Bade, *Corporate Responsibility and U.S. Import Regulations against Forced Labor*, 8 TULSA J COMP. & INT'L L. 5, 8 (2000).

²⁴ See CIMINO-ISAACS ET AL., *supra* note 4, at 7.

²⁵ See Reade & Witten, *supra* note 9.

²⁶ See Spencer Howard, *The Smoot-Hawley Tariff of 1930*, NAT'L ARCHIVES: HOOVER HEADS (Mar. 14, 2018), <https://hoover.blogs.archives.gov/2018/03/14/the-smoot-hawley-tariff-of-1930/> [<https://perma.cc/8H8X-VHF2>].

²⁷ See *The Senate Passes the Smoot-Hawley Tariff*, UNITED STATES SENATE: HISTORICAL HIGHLIGHTS, https://www.senate.gov/artandhistory/history/minute/Senate_Passes_Smoot_Hawley_Tariff.htm [<https://perma.cc/4C88-HDL2>].

²⁸ *Id.*

²⁹ See *id.*

³⁰ See *id.*

1930.³¹ The goal of the Smoot-Hawley Tariff Act, also known as the Tariff Act of 1930 (“Tariff Act”), was to use tariff increases to protect U.S. industries.³² The Tariff Act indiscriminately raised taxes on thousands of imports to stabilize the economy and protect American farmers.³³

B. Section 307: The Forced Labor Prohibition

Section 307 was included in the Tariff Act to prohibit the importation of goods made with forced labor.³⁴ Barring entry of merchandise produced with forced labor protects domestic producers by creating a fair market, as goods produced with forced labor inherently cost less to produce.³⁵ The current language of Section 307 reads:

All goods, wares, articles, and merchandise mined, produced, or manufactured wholly or in part in any foreign country by convict labor or/and forced labor or/and indentured labor under penal sanctions shall not be entitled to entry at any of the ports of the United States, and the importation thereof is hereby prohibited, and the Secretary of the Treasury is authorized and directed to prescribe such regulations as may be necessary for the enforcement of this provision.³⁶

Section 307 defines forced labor as: “[A]ll work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily. For the purposes of this section, the term ‘forced labor or/and indentured labor’ includes forced or indentured child labor.”³⁷ This Note incorporates this definition when referencing forced labor.

1. How Did We Get Here? The History and Development of Section 307

Prior to the Tariff Act, the United States already prohibited importing goods made with forced or penal labor in an effort to protect domestic labor.³⁸ After the United States abolished formal slavery in 1865, manufacturers and labor activists expressed increasing concern with unfair competition from forced labor, particularly domestic and international prison labor.³⁹ Activists argued that prohibiting the importation of goods produced with forced labor would raise labor standards globally and increase the price of imports so that

³¹ *See id.*

³² *See The Battle of Smoot-Hawley*, *ECONOMIST*, Dec. 20, 2008.

³³ *See id.*

³⁴ *See* 19 U.S.C. § 1307 (2018).

³⁵ *See The Battle of Smoot-Hawley*, *supra* note 32.

³⁶ 19 U.S.C. § 1307 (2018).

³⁷ *Id.*

³⁸ *See* CIMINO-ISAACS ET AL., *supra* note 4, at 3.

³⁹ *See id.*

domestically produced goods could compete with foreign imports.⁴⁰ In the absence of regulation, an imported good produced by forced labor could be cheaper for U.S. consumers than comparable domestic goods made using fair labor, resulting in unfair competition.⁴¹ To address that concern, Congress prohibited importing products “manufactured wholly or in part” by convict labor in 1890.⁴²

In the Tariff Act, Congress incorporated and expanded this prohibition to include *any* products of convict, forced, or indentured labor.⁴³ If a good was produced using a raw material extracted with prohibited forced labor, even if the manufacturing process itself did not use forced labor, the product was still barred from import.⁴⁴ However, Section 307 provided an exception—the consumptive demand exception—which allowed importation of goods produced with convict, forced, or indentured labor if the United States could not produce enough of that same product domestically to meet consumption.⁴⁵ This exception was read narrowly by the United States Court of International Trade, which found that the exception did not apply to products of prison labor.⁴⁶ Overall, general humanitarian concerns supported this exception.⁴⁷ The earlier text of Section 307 had primarily demonstrated concern with protecting domestic producers and workers but also wanted to ensure continued access to products made with forced labor in the supply chain that were inaccessible in the United States otherwise.⁴⁸

C. Section 307 Enforcement

1. Historical Enforcement of Section 307

From its inception and through the early 1990s, Section 307 was used sparingly to bar imports.⁴⁹ The United States International Trade Commission (“USITC”) found that the U.S. Customs Service (CBP’s predecessor) applied Section 307 leniently.⁵⁰ The USITC reported that “[b]etween 1930 and the mid-1980s, [the USITC] identified between 60 and 75 instances in which

⁴⁰ *See id.*

⁴¹ *See id.*

⁴² *Id.* (quoting Tariff Act of 1890 § 51, 26 Stat. 567, 624 (1890)).

⁴³ *See id.*

⁴⁴ *See* Bade, *supra* note 23, at 7.

⁴⁵ *See id.* at 8.

⁴⁶ *See generally* China Diesel Imports v. United States, 18 Ct. Int’l Trade 1086 (1994); *see also* Bade, *supra* note 23, at 8.

⁴⁷ *See* Bade, *supra* note 23, at 7–8.

⁴⁸ *See* CIMINO-ISAACS ET AL., *supra* note 4, at 3.

⁴⁹ *See id.* at 4.

⁵⁰ *See id.*

parties requested, or the U.S. Customs Service . . . considered the application of Section 307. Only eight of those instances resulted in a good's exclusion from importation."⁵¹ It was not until the 1980s, against the backdrop of Cold War tensions and increased public awareness of forced labor practices in the Soviet Union and China, that Congress refocused on enforcing Section 307.⁵² By the early 1990s, CBP increased its enforcement of Section 307, issuing several Withhold Release Orders ("WROs")⁵³ per year to deny products entry into the United States.⁵⁴ However, enforcement declined between 2000 and 2015: CBP did not issue any WROs during that time period.⁵⁵

Despite reduced implementation of WROs, Congress remained interested in protecting against forced labor.⁵⁶ In 1998, Congress prohibited the use of funds to allow importation of goods with forced labor in the supply chain.⁵⁷ Additionally, Congress passed legislation against human trafficking and requiring that trade agreements include provisions to protect workers' rights.⁵⁸ In 2000, Congress amended the definition of forced labor to include child labor.⁵⁹

In February 2016, the Trade Facilitation and Trade Enforcement Act⁶⁰ was signed into law.⁶¹ The Act amended Section 307 to remove the consumptive demand exception,⁶² which CBP stated would permit a more comprehensive enforcement of Section 307 and create fairer conditions for American manufacturers by disallowing imports from foreign manufacturers undercutting

⁵¹ *Id.*

⁵² *See id.* at 4–5.

⁵³ Section 307 is enforced through WROs and Findings. *See* discussion *infra* Section I.C.2.

⁵⁴ *See* CIMINO-ISAACS ET AL., *supra* note 4, at 5. WROs are official documents issued by CBP that "bar the entry of certain goods suspected of being produced with forced labor." *Id.* at 1.

⁵⁵ *See id.* at 5–6.

⁵⁶ *See id.* at 6.

⁵⁷ *See id.*; Treasury and General Government Appropriations Act, 1998, Pub. L. No. 105-61, § 634, 111 Stat. 1272 (1997).

⁵⁸ *See* Victims of Trafficking and Violence Protection Act of 2000, Pub. L. No. 106-386, 114 Stat. 1464 (2000); *see also* Courtney Bubl , *How Can Federal Anti-Trafficking Efforts Advance Racial Equity?*, GOV'T EXEC. (Feb. 8, 2022), <https://www.govexec.com/management/2022/02/how-can-federal-anti-trafficking-efforts-advance-racial-equity/361741/> [<https://perma.cc/R38E-ZL7V>] (President Biden is emphasizing human trafficking efforts and seeking ways to advance racial equity throughout these efforts).

⁵⁹ *See* Trade and Development Act of 2000, Pub. L. No. 106-200, § 411, 114 Stat. 251 (2000) (codified at 19 U.S.C. § 1307).

⁶⁰ Trade Facilitation and Trade Enforcement Act of 2015 ("TFTEA"), Pub. L. No. 114-125, 130 Stat. 122, 239 (2016) (codified at 19 U.S.C. § 4301).

⁶¹ *See id.*

⁶² *See id.* § 910.

U.S. counterparts on price by using forced labor.⁶³ Enforcement of Section 307 has increased since Congress eliminated the exception.⁶⁴

Along with the removal of the consumptive demand exception, the Trump Administration focused on aggressively fighting unfair trade practices as part of its political agenda, which also influenced the increased enforcement of Section 307, particularly with respect to Chinese imports.⁶⁵ Between February 2016 and May 2021, CBP issued twenty-eight WROs.⁶⁶ Since 2016, CBP has issued geographic WROs; for example, since 2018, all Turkmenistan cotton or products containing Turkmenistan cotton have been barred from entry into the United States.⁶⁷ In 2020, WROs targeted Chinese goods including cotton and tomatoes.⁶⁸ The passage of the Countering America's Adversaries Through Sanctions Act of 2017⁶⁹ continued the trend of using trade as a political tool,⁷⁰ creating a presumption that merchandise connected to North Korean labor was produced using forced labor and is therefore barred from import into the United States.⁷¹

2. Current Enforcement of Section 307

This section explains Section 307 enforcement mechanisms (WROs and Findings) and demonstrates that CBP's investigatory process is veiled, which limits the importer's remedial options and stunts the importer's ability to comply with the prohibition on forced labor. CBP's enforcement of Section 307 is comprised of three stages: (1) investigation, (2) issuance of a WRO or

⁶³ See GAO-21-259, *supra* note 11, at 6.

⁶⁴ See CIMINO-ISAACS ET AL., *supra* note 4, at 7.

⁶⁵ See Reade & Witten, *supra* note 9.

⁶⁶ See CIMINO-ISAACS ET AL., *supra* note 4, at 7.

⁶⁷ See CIMINO-ISAACS ET AL., *supra* note 4, at 7; see also *Withhold Release Orders and Findings List*, U.S. CUSTOMS & BORDER PROT., <https://www.cbp.gov/trade/forced-labor/withhold-release-orders-and-findings/> [<https://perma.cc/N3SH-CKJF>] (last visited Sept. 8, 2022). Unlike traditional WROs which apply to a specific good either manufactured by a specific producer or in a specific facility, geographic WROs bar a type or category of good that is manufactured within a geographic region, regardless of the specific producer or facility. See CIMINO-ISAACS ET AL., *supra* note 4, at 7.

⁶⁸ See CIMINO-ISAACS ET AL., *supra* note 4, at 7; see also *Withhold Release Orders and Findings List*, *supra* note 67.

⁶⁹ 22 U.S.C. § 9241a (2018).

⁷⁰ See generally Thiemo Fetzer & Carlo Schwarz, *Trade, Tariffs and Politics: Evidence From the US, EU and China*, WORLD ECONOMIC FORUM (Apr. 29, 2019), <https://www.weforum.org/agenda/2019/04/tariffs-and-politics-evidence-from-trump-s-trade-wars/> [<https://perma.cc/L5JN-FXQK>].

⁷¹ This presumption may be rebutted by clear and convincing evidence that the goods were not produced with forced labor. See 22 U.S.C. § 9241a(b) (2018).

Finding, and (3) modification or revocation of a WRO or Finding.⁷² CBP's decision whether to modify or revoke a WRO or Finding can be challenged by an importer in the U.S. Court of International Trade, and such challenges are appealable to the United States Court of Appeals for the Federal Circuit.⁷³

a. Customs and Border Protection's Investigatory Process

CBP begins enforcement of Section 307 after receiving a report, also called a petition, that an import is a product of forced labor.⁷⁴ The allegations comprising a report may come from other U.S. agencies, media reports, scholars, non-governmental organizations, or any person who has reason to believe that merchandise that is being imported, or is likely to be imported, has any forced labor in its supply chain.⁷⁵ Customs officers are required to report any reasonable belief that an import is connected to forced labor to CBP's Commissioner, who must initiate an investigation.⁷⁶

Within thirty days of receiving the petition, CBP's Forced Labor Division conducts a preliminary review of the petition and decides whether to accept or reject the petition for investigation or refer the petition to another agency for further investigation into violations of other laws.⁷⁷ If the petition is accepted, CBP commences an investigation.⁷⁸ Depending on the facts and specifics of the report, the investigation's timing, scope, and scale vary.⁷⁹

During the initial investigatory phase (90–180 days following the initiation of the investigation), the Commissioner attempts to corroborate facts, collects evidence, and analyzes the circumstances to determine whether there is a reasonable suspicion of a Section 307 violation.⁸⁰ If the investigation finds a reasonable suspicion of forced labor in the supply chain, the Commissioner, following a legal review, issues a WRO.⁸¹ The WRO is then published, and

⁷² See CIMINO-ISAACS ET AL., *supra* note 4, at 8.

⁷³ See 28 U.S.C. § 1295 (2018).

⁷⁴ See CIMINO-ISAACS ET AL., *supra* note 4, at 8.

⁷⁵ See 19 C.F.R. § 12.42 (2021); CIMINO-ISAACS ET AL., *supra* note 4, at 8.

⁷⁶ See 19 C.F.R. § 12.42(a); CIMINO-ISAACS ET AL., *supra* note 4, at 8; U.S. DEP'T OF HOMELAND SEC., FORCED LABOR ENFORCEMENT TASK FORCE: ESTABLISHING TIMELINES 17–18 (July 30, 2021) [hereinafter ESTABLISHING TIMELINES].

⁷⁷ See ESTABLISHING TIMELINES, *supra* note 76, at 16.

⁷⁸ See *id.* at 16.

⁷⁹ See U.S. CUSTOMS & BORDER PROT., NO. 1547-0921, WHAT ARE THE TIMELINES AND INVESTIGATIVE BENCHMARKS FOR FORCED LABOR PETITIONS? (Sept. 30, 2021), <https://www.cbp.gov/document/fact-sheets/slick-sheet-cbp-timelines-and-investigative-benchmarks-forced-labor-petitions> [<https://perma.cc/H8Z2-7657>].

⁸⁰ See *id.*; ESTABLISHING TIMELINES, *supra* note 76, at 18–20.

⁸¹ See ESTABLISHING TIMELINES, *supra* note 76, at 19.

CBP sends a notice to the importer.⁸² In the second phase (typically 180–365 days following the initiation of the investigation), CBP evaluates whether it has probable cause to believe that there is forced labor in the supply chain of the imported good.⁸³ If CBP determines there is probable cause of the presence of forced labor, a Finding is then issued and published, following review for legal sufficiency.⁸⁴

b. Merchandise Is Detained Pursuant to WROs and Findings

CBP is “responsible for preventing the entry of products made with forced labor into the U.S. market by investigating and acting upon allegations of forced labor in supply chains.”⁸⁵ CBP enforces Section 307 by issuing WROs and Findings, which requires merchandise be barred from entry into the United States.⁸⁶ CBP issues a WRO when there is “reasonable evidence” of the use of forced labor in the supply chain.⁸⁷ A WRO indicates a product should be denied entry into the United States or detained due to suspicion of forced labor being used in the supply chain.⁸⁸ CBP issues a Finding when there is “conclusive evidence” that there is forced labor in the supply chain of a good, allowing CBP to seize the merchandise.⁸⁹ WROs and Findings are in place until modified or revoked.⁹⁰ CBP’s Forced Labor Division investigates allegations of forced labor and collects evidence in support of the WRO or Finding.⁹¹

c. Revoking and Modifying WROs and Findings

After a WRO or Finding is issued and published, an importer may request that it be revoked or modified.⁹² Additionally, if goods are subject to a WRO

⁸² See GAO-21-259, *supra* note 11, at 14.

⁸³ See *id.* at 13.

⁸⁴ See ESTABLISHING TIMELINES, *supra* note 76, at 19; GAO-21-259, *supra* note 11, at 13.

⁸⁵ *Forced Labor*, U.S. CUSTOMS & BORDER PROT., <https://www.cbp.gov/trade/forced-labor> [<https://perma.cc/TS3X-YE66>] (last visited Sept. 8, 2022). Other state and federal agencies, non-governmental organizations, and private sector entities conduct activities and collect information related to forced labor. See GAO-21-259, *supra* note 11, at 6.

⁸⁶ See U.S. CUSTOMS & BORDER PROT., No. 1565-1020, HOW DOES CBP ENFORCE 19 U.S.C. § 1307? (Jan. 28, 2022), <https://www.cbp.gov/document/fact-sheets/how-does-cbp-enforce-19-usc-1307> [<https://perma.cc/N72W-FKUA>].

⁸⁷ A WRO may be issued for a good, or a type of good, from a specific manufacturer, location, or region. See *Withhold Release Orders and Findings List*, *supra* note 67.

⁸⁸ See HOW DOES CBP ENFORCE 19 U.S.C. § 1307?, *supra* note 86.

⁸⁹ *Withhold Release Orders and Findings List*, *supra* note 67.

⁹⁰ See GAO-21-259, *supra* note 11, at 10–11.

⁹¹ See *id.* at 12. A list of current WROs and Findings are published and can be found at CBP’s website. See *Withhold Release Orders and Findings List*, *supra* note 67.

⁹² See GAO-21-259, *supra* note 11, at 14.

and denied entry into the U.S. market, an importer has two other options that are not revoking or modifying the WRO: (1) re-export its goods⁹³ or (2) provide evidence showing that the goods were not produced with forced labor.⁹⁴ If an importer chooses to re-export its goods, the importer must show that the goods will not be sold in the United States.⁹⁵ When re-exporting goods, the importer does not have to show lack of forced labor in its supply chain.⁹⁶ However, if an importer wants to sell the goods in the United States, or if the goods were seized pursuant to a Finding, the importer must provide evidence that there is no forced labor involved.⁹⁷

A successful modification results in the suspension of WRO enforcement once the indicators of forced labor have been remediated.⁹⁸ CBP requests companies to demonstrate that forced labor is not present in the supply chain, or alternatively demonstrate the implementation of remediation plans.⁹⁹ CBP does not, however, provide companies with guidance to address the risks of forced labor in supply chains or how to implement due diligence practices, even though CBP will not modify or revoke a WRO or Finding unless all forced labor indicators are remediated.¹⁰⁰ On the other hand, revocation results in removal of the merchandise from the scope of the WRO or Finding once CBP has determined that there is no connection to forced labor.¹⁰¹ If the importer successfully contests a WRO or Finding, the merchandise may be released and enter the United States.¹⁰² However, if the request to modify or revoke a WRO is unsuccessful, the importer has the opportunity to remove the merchandise at issue from the United States or re-export it within sixty days.¹⁰³ If sixty days pass and the importer does not regain possession of their merchandise, CBP may seize and destroy it.¹⁰⁴

⁹³ Merchandise seized pursuant to a Finding may not be re-exported. *See* 19 C.F.R. § 12.44.

⁹⁴ *See id.* § 12.43.

⁹⁵ *See id.* § 12.44.

⁹⁶ *See id.* § 12.44.

⁹⁷ *See id.* § 12.43.

⁹⁸ *See id.*

⁹⁹ *See* GAO-21-259, *supra* note 11, at 16.

¹⁰⁰ *See id.*

¹⁰¹ *See* U.S. CUSTOMS & BORDER PROT., NO. 1394-0321, FACT SHEET: WRO MODIFICATION/REVOCATION PROCESS OVERVIEW (Mar. 8, 2021), <https://www.cbp.gov/document/fact-sheets/wro-modificationrevocation-processes-overview> [<https://perma.cc/U332-Z3GG>] [hereinafter WRO MODIFICATION/REVOCATION OVERVIEW].

¹⁰² *See* 19 C.F.R. § 12.43(c).

¹⁰³ *See id.* § 12.44(a); CIMINO-ISAACS ET AL., *supra* note 4, at 9.

¹⁰⁴ *See* 19 C.F.R. § 12.44(b); CIMINO-ISAACS ET AL., *supra* note 4, at 9.

(1.) Federal Regulations Instruct Importers on the Required Supporting Documentation

Federal regulations direct importers to submit specific documentation to modify or revoke a WRO or Finding.¹⁰⁵ The regulations indicate that in order for an importer to succeed in its request to modify or revoke a WRO or Finding, the importer must demonstrate that it made every reasonable effort to determine the source of materials and labor used in production of the merchandise and its components.¹⁰⁶ An importer attempting to demonstrate lack of forced labor in its supply chain must provide documentation including certificates of origin signed by the foreign seller or owner of the good and a statement of evidence.¹⁰⁷ If any stage of production occurred in a country different from the country of ultimate export to the United States, regulations require an additional signed certification.¹⁰⁸ The statement of evidence should demonstrate evidence of a diligent investigation into the supply chain, permissible labor (indicating lack of forced labor), and a pre-existing method for evaluating the supply chain.¹⁰⁹ This information must include a statement “of the ultimate consignee of the merchandise”¹¹⁰ showing that the importer has made every “reasonable effort” to determine the source of the materials, the production process, and the category of labor used at each stage of production.¹¹¹ These regulations do not define what constitutes a reasonable effort.¹¹² The statement must also contain the complete result of the importer’s investigation into the presence of forced labor in the supply chain, including the importer’s belief as to the character of the labor present at every stage of production.¹¹³ Once these documents are timely submitted, it is within CBP’s discretion to determine whether the merchandise is admissible.¹¹⁴

¹⁰⁵ See 19 C.F.R. § 12.43.

¹⁰⁶ See *id.* § 12.43(b).

¹⁰⁷ See *id.* § 12.43.

¹⁰⁸ See *id.* § 12.43(a).

¹⁰⁹ See Ericka Johnson et al., *Strategies for Responding to Withhold Release Orders*, INST. FOR SUPPLY MGMT. (May 2021), <https://www.ismworld.org/supply-management-news-and-reports/news-publications/inside-supply-management-magazine/blog/2021/2021-05/strategies-for-responding-to-withhold-release-orders/> [<https://perma.cc/QY76-9SDA>].

¹¹⁰ The consignee is the U.S. party to whom the foreign shipper sold the imported goods. See U.S. CUSTOMS & BORDER PROT., CUSTOMS DIRECTIVE NO. 3550-079A, ULTIMATE CONSIGNEE AT TIME OF ENTRY OR RELEASE, https://www.cbp.gov/sites/default/files/documents/3550_079a_3.pdf [<https://perma.cc/2E4C-PP82>] (Nov. 26, 2018).

¹¹¹ 19 C.F.R. § 12.43(b).

¹¹² See generally *id.* §§ 12.43–.44.

¹¹³ See *id.* § 12.43(b).

¹¹⁴ See *id.* § 12.43(c).

(2.) Customs and Border Protection Rulings on Importers' Requests for Modification

In addition to the regulations, CBP rulings on WRO or Finding modification and revocation requests provide importers further information as to what documentation is necessary to overcome a WRO or Finding.¹¹⁵ In one ruling, CBP concluded the importer had failed to demonstrate that its merchandise was not made with forced labor because the importer did not provide substantial evidence to allow CBP to determine that the entities that processed the merchandise's raw material did so without relying on forced labor.¹¹⁶ Specifically, the ruling indicated the submission lacked production and processing records of the raw material used and the production processes for several stages of production.¹¹⁷ CBP noted additional failings: the certificate was not precise enough because it did not describe the specific products produced, the dates of transaction, and the locations of factories.¹¹⁸ Moreover, CBP stated the Code of Conduct letter was neither current nor recent, and the included invoices did not reflect the shipment.¹¹⁹ In another ruling issued to the same importer, CBP found similar deficiencies in the evidence provided.¹²⁰ CBP cited unsigned or undated customs declarations, illegible contracts, lack of specificity in the delivery list, and purchase orders that did not contain signatures or locations for those involved.¹²¹

(3.) Customs and Border Protection's Guidance to Importers Protesting Modification

Finally, CBP has also published fact sheets to provide guidance to importers when protesting a CBP decision.¹²² CBP's website provides tips and guidance regarding the evidence importers should provide to modify or revoke

¹¹⁵ See *Trade Compliance Flash: CBP's Latest Forced Labor Rulings Offer Insight into Documents Needed to Overcome Import Detentions*, MILLER & CHEVALIER (June 7, 2021), <https://www.millerchevalier.com/publication/trade-compliance-flash-cbps-latest-forced-labor-rulings-offer-insight-documents-needed> [<https://perma.cc/TH5Z-RWPB>].

¹¹⁶ See *id.*

¹¹⁷ See *id.*

¹¹⁸ See *id.*

¹¹⁹ See *id.*

¹²⁰ See *id.*

¹²¹ See generally *id.*

¹²² See, e.g., U.S. CUSTOMS & BORDER PROT., NO. 1165-0620, FACT SHEET: HELPFUL HINTS FOR SUBMITTING PROOF OF ADMISSIBILITY AND WRO REVOCATION/MODIFICATION REQUESTS (Aug. 12, 2020), <https://www.cbp.gov/document/fact-sheets/fact-sheet-helpful-hints-submitting-proof-admissibility> [<https://perma.cc/JBE2-GZ8S>] [hereinafter SUBMITTING PROOF OF ADMISSIBILITY].

a WRO or Finding.¹²³ CBP explains that copies of policies and evidence of implementation, recent and unannounced third-party audits, remediation plans, photographs of living and working accommodations, and detailed supply chain maps specifying locations of manufacturers, factories, farms, and processing centers will all be helpful.¹²⁴ CBP suggests an importer's request should include the results of a credible audit, a corrective action plan and its implementation, and evidence of remediation of forced labor indicators.¹²⁵ CBP defines a credible audit as an "unannounced independent, third-party audit," based on interviews completed in the native language, which must address all indicators of forced labor.¹²⁶ CBP further explains that a corrective action plan outlines all audit findings, necessary actions to remedy forced labor indicators, proof of implementation of forced labor indicator remediation, a clear timeline of remediation, and consequences for the failure to complete the corrective action plan.¹²⁷ However, CBP also cautions that importers should avoid document dumps, providing policies without explaining how they will be implemented, and presenting information regarding efforts to detect forced labor without including additional details on efforts to combat it.¹²⁸

II. Analysis

After a WRO or Finding is issued and published, an importer may request that it be revoked or modified.¹²⁹ This process can prove challenging for importers as the regulations and CBP's guidance are unclear as to how a WRO or Finding may be revoked or modified.¹³⁰ To succeed in a request to modify

¹²³ See *id.*

¹²⁴ See *id.*

¹²⁵ See WRO MODIFICATION/REVOCATION PROCESS OVERVIEW, *supra* note 101.

¹²⁶ U.S. CUSTOMS & BORDER PROT., NO. 1561-1021, WHAT IS IN A PETITION FOR A WRO AND/OR FINDING MODIFICATION OR REVOCATION? (Oct. 4, 2021), <https://www.cbp.gov/document/fact-sheets/what-petition-wro-andor-finding-modification-or-revocation> [<https://perma.cc/58HD-84TZ>] [hereinafter WHAT IS IN A PETITION FOR A WRO]. The International Labour Organization's indicators of forced labor are: "abuse of vulnerability, deception, restriction of movement, isolation, physical and sexual violence, intimidation and threats, retention of identity documents, withholding of wages, debt bondage, abusive working and living conditions, [and] excessive overtime." Int'l Lab. Org. [ILO], *ILO Indicators of Forced Labour*, at 3 (Oct. 1, 2012), https://www.ilo.org/wcmsp5/groups/public/—ed_norm/—declaration/documents/publication/wcms_203832.pdf [<https://perma.cc/VLF2-TLMD>].

¹²⁷ See WHAT IS IN A PETITION FOR A WRO AND/OR FINDING MODIFICATION OR REVOCATION?, *supra* note 126.

¹²⁸ See SUBMITTING PROOF OF ADMISSIBILITY, *supra* note 122.

¹²⁹ See GAO-21-259., *supra* note 11, at 14.

¹³⁰ See *id.* at 26, 28–29.

or revoke a WRO or Finding, the importer must demonstrate that “he had made every reasonable effort to determine the source of the merchandise and of every component thereof and to ascertain the character of labor used in the production of the merchandise and each of its components.”¹³¹ However, the evidentiary standard is unclear. In addition to the regulations, CBP only provides “helpful hints” as to what documentation is sufficient to revoke or modify a WRO and prove goods are not connected to forced labor and are thus admissible into the United States.¹³² While CBP’s published rulings are enlightening, they are vague pronouncements that do little to advise other importers on the required evidence. Moreover, importers only have three months from the issuance of notice that their merchandise is being detained to contest the issue, after which CBP evaluates the request and engages in dialogue with the importer.¹³³ Additionally, the detention notice provides importers with limited information—it does not specify why merchandise was detained and fails to elaborate on CBP’s basis for exclusion, which makes it difficult for importers to challenge their merchandise’s exclusion.¹³⁴ Not only is the lack of clarity creating challenges for importers, but gathering evidence to demonstrate the lack of presence of forced labor in their supply chains is also difficult as they are not required to consistently collect this type of information and attempting to gather this evidence after there is a problem is time consuming and expensive.

Even if an importer ostensibly provides the required documentation, CBP can deem the information insufficient to revoke or modify a WRO or Finding.¹³⁵ CBP provides guidance regarding the documentation an importer may additionally present; that guidance, however, is not determinative, and CBP has discretion to deny the importer’s request.¹³⁶ An importer will have difficulty demonstrating that forced labor is not present in its supply chain because of the ambiguous guidance from CBP on what documentation is sufficient to revoke or modify the WRO or Finding. Effective enforcement of Section 307 is necessary if the United States wants to prohibit forced labor globally; however, without clear guidance, importers will struggle to comply.

¹³¹ 19 C.F.R. § 12.43(b) (2021).

¹³² SUBMITTING PROOF OF ADMISSIBILITY, *supra* note 122.

¹³³ See 19 C.F.R. § 12.43(a); CIMINO-ISAACS ET AL., *supra* note 4, at 9; see also WRO MODIFICATION/REVOCATION PROCESS OVERVIEW, *supra* note 101.

¹³⁴ See *Trade Compliance Flash: First Court Challenge to CBP Enforcement of Withhold Release Order*, MILLER & CHEVALIER (May 14, 2021), <https://www.millerchevalier.com/publication/trade-compliance-flash-first-court-challenge-cbp-enforcement-withhold-release-order> [<https://perma.cc/N4KT-3TTQ>].

¹³⁵ See *id.*

¹³⁶ See 19 C.F.R. §§ 12.43–.44.

This part first analyzes why it is so difficult for an importer to challenge CBP's detainment or seizure of merchandise by outlining the flaws of CBP's regulations, rulings, and guidance. Ultimately, CBP does not provide importers with clear guidance, making it challenging for importers to produce the documentation and evidence CBP needs to determine whether forced labor is present at any stage of the supply chain. Second, this part considers the current litigation of Virtus Nutrition's challenge to CBP's denial of a modification of a WRO. The outcome of this litigation may impact the way importers challenge CBP determinations and may force CBP to amend and clarify its guidance. If Virtus Nutrition is successful, it could open the doors for future litigation challenging CBP decisions. Third, the U.S. Uyghur Forced Labor Protection Act is discussed in the context of examining the way an importer can overcome a presumption of forced labor. Finally, this part explores international due diligence guidelines which can inform an importer's efforts to prevent and mitigate forced labor in its supply chain and can serve as a framework for potential U.S. legislation.

A. Customs and Border Protection's Regulations, Rulings, and Guidance Do Not Provide Clear Instructions to Importers

1. Federal Regulations

While federal regulations direct importers to submit specific documentation to modify or revoke a WRO or Finding, the regulations only identify the minimum required support an importer must establish.¹³⁷ The regulations indicate that to succeed in its request to modify or revoke a WRO or Finding, the importer must demonstrate that every reasonable effort has been made to determine the source of materials and labor used in the production process of the merchandise and each of its components.¹³⁸ However, the regulations do not define what is meant by "reasonable effort." The regulations only state that the importer must provide documentation including certificates of origin and a statement of evidence and then describe what these documents should entail.¹³⁹ However, despite an importer's compliance with the regulations, it is still within CBP's discretion to determine whether the information proves there is no forced labor in the supply chain and whether that merchandise is admissible.¹⁴⁰

In making its determination, CBP does not provide an evidentiary standard of proof an importer must meet to overcome a WRO or Finding.¹⁴¹ The regu-

¹³⁷ See *id.* § 12.43.

¹³⁸ See *id.* § 12.43(b).

¹³⁹ See *id.* § 12.43.

¹⁴⁰ See *id.* § 12.43(c).

¹⁴¹ See *id.* § 12.43.

lations only outline the minimum documentation an importer must provide to CBP, and after the submission of this required documentation, CBP may still decline to revoke or modify its WRO or Finding.¹⁴² It is difficult for an importer to prove that the supply chain of its merchandise does not contain any evidence of forced labor because of the lack of clarity from CBP on what documentation is sufficient to overcome the WRO or Finding.

2. Customs and Border Protection Rulings

WRO or Finding modification and revocation rulings provide importers greater insight into the documentation required to overcome a WRO or Finding. However, the rulings further illustrate the lack of clarity in the regulations. While recent CBP rulings have demonstrated insufficiencies in documentation provided by importers, they do little to shed light on what types of records would be sufficient to demonstrate the cleanliness of the supply chains.

In what appears to be the first instance since the early 1990s in which CBP has modified a Finding, CBP determined that disposable gloves produced by Top Glove in Malaysia were no longer being made with prohibited labor following Top Glove's additional evidence.¹⁴³ CBP explained the Finding would not be used against Top Glove because it had addressed all International Labour Organization ("ILO") indicators of forced labor, improved working and living conditions, and made remediation payments.¹⁴⁴ CBP did not, however, provide information about the particular evidence that CBP found to be sufficient in making its determination.¹⁴⁵ Instead, CBP simply stressed that its inquiries into revocation or modification of rulings are fact-specific.¹⁴⁶ While this type of CBP ruling—a ruling in response to an importer's request to revoke or modify a WRO—is enlightening, it highlights the complexity and ambiguity surrounding an importer's challenge to CBP's WROs and Findings because CBP fails to identify what evidence is sufficient and what facts it relied upon to make its decisions.¹⁴⁷

¹⁴² *See id.*

¹⁴³ *See* Determination that Maintenance of Finding of March 29, 2021, Pertaining to Certain Disposable Gloves Produced in Malaysia, Is No Longer Necessary, 86 Fed. Reg. 50,725 (Sept. 10, 2021).

¹⁴⁴ *See CBP Modifies Forced Labor Finding on Top Glove Corporation Bhd.*, U.S. CUSTOMS & BORDER PROT. (Sept. 10, 2021), <https://www.cbp.gov/newsroom/national-media-release/cbp-modifies-forced-labor-finding-top-glove-corporation-bhd> [<https://perma.cc/63DK-ANZU>].

¹⁴⁵ *See id.*

¹⁴⁶ *See id.*

¹⁴⁷ *See id.*

3. Customs and Border Protection's Guidance

Because the regulations are vague, CBP has published fact sheets to assist importers in their challenges to CBP.¹⁴⁸ CBP's website provides tips and guidance to importers for what evidentiary proof they should offer to prove admissibility or modify or revoke a WRO or Finding.¹⁴⁹ The tips CBP has published provide color to the regulations and provide examples to importers as to what types of records could satisfy the regulations.¹⁵⁰ However, once the importer submits a request, CBP does its own evaluation and requests that the importer provide particular documentation.¹⁵¹ CBP then makes a decision based on the remediation of forced labor indicators.¹⁵² While CBP can detain merchandise and issue a WRO based on information that provides reasonable suspicion, but not conclusive evidence, of forced labor, the burden is on the importer to prove the admissibility of its merchandise.¹⁵³ However, the guidance importers must follow is unclear because even if an importer follows the guidance, CBP has the discretion to decide the evidence offered is insufficient and continue to bar the import from entry into U.S. ports.¹⁵⁴ But without transparent decision making and clear guidance, importers cannot effectively challenge CBP decisions, making it more difficult for the United States to combat forced labor globally.

B. Virtus Nutrition LLC v. United States Challenges CBP's Section 307 Enforcement

These challenges brought by importers contesting CBP decisions are playing out in the *Virtus Nutrition* litigation, in which Virtus Nutrition LLC ("Virtus Nutrition") argues it followed CBP's guidance and submitted the proper documentation, thus providing sufficient evidence proving forced labor is not present in its merchandise's supply chain.¹⁵⁵ In the first case of its kind,¹⁵⁶ Virtus Nutrition sued CBP because it alleges that it has provided the documentation CBP has requested, yet CBP maintains the evidence is insufficient.¹⁵⁷ This case directly results from CBP's unclear and inadequate

¹⁴⁸ See SUBMITTING PROOF OF ADMISSIBILITY, *supra* note 122.

¹⁴⁹ See *id.*

¹⁵⁰ See *id.*

¹⁵¹ See WRO MODIFICATION/REVOCATION PROCESS OVERVIEW, *supra* note 101.

¹⁵² See *id.*

¹⁵³ See *id.*

¹⁵⁴ See *id.*

¹⁵⁵ See Complaint ¶¶ 9–10, 13–14, *Virtus Nutrition LLC v. United States*, No. 1:21-cv-00165 (Ct. Int'l Trade Apr. 15, 2021).

¹⁵⁶ See generally *id.*

¹⁵⁷ See *id.* ¶¶ 9–10, 13.

guidance for importers to demonstrate that there is no forced labor in the production of their goods.

Pursuant to a WRO, CBP detained a shipment of products containing palm oil from Malaysia.¹⁵⁸ The plaintiff, Virtus Nutrition, filed a complaint to contest the denial of its protest and to challenge the WRO (which prevented importation of merchandise containing palm oil fatty acid distillates and palm stearin originating in Malaysia).¹⁵⁹ In the notice, CBP indicated the merchandise was barred from import pursuant to Section 307 but it provided no rationale for its continued suspicion of forced labor.¹⁶⁰ The notice stated only that the information Virtus Nutrition had submitted was insufficient to persuade CBP to revoke or modify the December 30, 2020 WRO on palm oil and palm oil-containing products linked to Sime Darby Plantation.¹⁶¹ Virtus Nutrition challenged CBP's decision to exclude the merchandise as arbitrary and capricious.¹⁶² Virtus Nutrition argued it provided CBP with the requested documentation regarding the manufacturing of the product, including the growth and harvesting of the raw fruit and the extraction and refining of oils from the palm fruit, which demonstrates the merchandise is not connected to Sime Darby Plantation and therefore should not be subject to the WRO.¹⁶³

Other companies are taking interest in this litigation.¹⁶⁴ For example, American Apparel & Footwear Association ("AAFA"), "a national trade association representing footwear, apparel, and other sewn product companies and suppliers,"¹⁶⁵ moved to file an amicus brief.¹⁶⁶ In its motion, AAFA stated that "[it] strongly support[s] the forced labor statute and efforts to end the forced labor scourge globally. However, the enforcement of that statute by CBP has been marked by lack of due process, an unreasonable standard of evidence, lack of transparency, and arbitrary and capricious decisions."¹⁶⁷

¹⁵⁸ See *id.* ¶¶ 5–8.

¹⁵⁹ See *id.* ¶ 1.

¹⁶⁰ See *id.* ¶ 15.

¹⁶¹ See *id.*

¹⁶² See *id.* ¶¶ 9–12, 16.

¹⁶³ See *id.* ¶ 9.

¹⁶⁴ See generally Memorandum In Support of Motion for Leave to File a Brief as Amicus Curiae at 4, *Virtus Nutrition*, No. 1:21-cv-00165 (Aug. 26, 2021).

¹⁶⁵ *About*, AM. APPAREL & FOOTWEAR ASS'N., <https://www.aafaglobal.org/AAFA/About/AAFA/AboutAAFA.aspx?hkey=24ca44d3-812d-466c-85d0-4def350f9a37> [https://perma.cc/43DG-6DGJ] (last visited Sept. 25, 2022).

¹⁶⁶ See generally Motion for Leave to File a Brief as Amicus Curiae, *Virtus Nutrition*, No. 1:21-cv-00165 (Aug. 26, 2021).

¹⁶⁷ Memorandum in Support of Motion for Leave to File a Brief as Amicus Curiae at 1–2, *Virtus Nutrition*, No. 1:21-cv-00165 (Aug. 26, 2021).

This case is unlikely to be resolved by a judicial ruling, as the parties have indicated that they will likely resolve the matter without further litigation.¹⁶⁸ Should the case continue, the court's ruling would hopefully clarify what importers must show to combat CBP exclusion of goods from entry into U.S. ports. Though the court's ruling would guide other importers, it would be tailored to the *Virtus Nutrition* case and therefore would not be significantly more useful as a guide than previous rulings. Even if the decision is broader, CBP could continue to state that its inquiry is fact-specific—and the documentation it deems sufficient in one scenario may be deemed insufficient in another. Nonetheless, a ruling revealing that CBP regulations and guidance are unclear might encourage CBP to clarify its regulations. This case, even without final judicial resolution, will likely lead other importers to pursue legal action against CBP.

C. Uyghur Forced Labor Prevention Act Sheds Light on a Standard of Proof

In December 2021, President Biden signed the Uyghur Forced Labor Prevention Act¹⁶⁹ into law, which creates a rebuttable presumption that forced labor is present in the supply chain of merchandise produced in, wholly or in part, or sourced from China's Xinjiang Uyghur Autonomous Region.¹⁷⁰ Therefore, no merchandise from this region is permitted into the United States, pursuant to Section 307, even without a producer or facility-specific WRO or any specific showing of the presence of forced labor in the supply chain.¹⁷¹

An importer may rebut this presumption of forced labor if it can produce a record that fully complies with the Forced Labor Enforcement Task Force's¹⁷² ("FLETF") due diligence and evidentiary guidance.¹⁷³ This record must be supplemented by any "implementing regulations" and a showing that the importer has "completely and substantively responded to all inquiries

¹⁶⁸ See Consent Motion to Stay Defendant's Response to the Motion Made by American Apparel and Footwear Association to File a Brief as *Amicus Curiae* in this Action at 2, *Virtus Nutrition*, No. 1:21-cv-00165 (Mar. 3, 2022); see generally Joint Status Report, *Virtus Nutrition*, No. 1:21-cv-00165 (July 11, 2022).

¹⁶⁹ Pub. L. 117-78 § 3, 135 Stat. 1525–32 (2021).

¹⁷⁰ See *id.* § 3(e).

¹⁷¹ See *id.*

¹⁷² Through executive order, in 2020, President Trump created the Forced Labor Enforcement Task Force to improve coordination efforts among U.S. agencies to prohibit the importation of forced labor merchandise. See Exec. Order No. 13,923, 85 Fed. Reg. 30,587 (May 15, 2020). Implementation of this task force indicates the need to oversee CBP's enforcement efforts to ensure the effectiveness of Section 307's goal to continue the prohibition of forced labor.

¹⁷³ See Uyghur Forced Labor Prevention Act § 3(b).

for information submitted by” CBP.¹⁷⁴ The documents produced must demonstrate through “clear and convincing evidence” that the goods were not produced wholly or in part with forced labor.¹⁷⁵ Companies have expressed concern that this rebuttable presumption is in fact irrebuttable, as neither the Act nor CBP regulations with regard to Section 307 specify what evidence is sufficient to rebut the presumption of forced labor in the supply chain by clear and convincing evidence.¹⁷⁶

In an effort to mitigate importers’ challenges in complying with Section 307, the Act charges the FLETF with publishing an enforcement strategy.¹⁷⁷ Congress recognized that the lack of clarity in the guidance is an issue when it required the FLETF to publish an enforcement strategy.¹⁷⁸ The enforcement strategy contains a list of entities and products involved in forced labor.¹⁷⁹ The FLETF established a clear and convincing evidentiary standard that importers must demonstrate to rebut the presumption.¹⁸⁰ However, the FLETF states that CBP’s determination on whether or not a good was mined, produced, or manufactured, wholly or in part, in China’s Xinjiang Uyghur Autonomous Region is a fact-based determination, and there is no de minimis threshold.¹⁸¹ The strategy also includes guidance to importers with respect to forced labor due diligence.¹⁸² In general, CBP requires evidence be presented in a well-organized manner and in English.¹⁸³ This evidence must demonstrate that the indicators of forced labor are not present or are remediated.¹⁸⁴ Importers must provide information regarding their workforce—including the circumstances of their employment and evidence of payment, in addition to quantitative information such as how many workers work at a facility and the total input and output volume of goods or materials.¹⁸⁵ Further, importers must be readily

¹⁷⁴ *Id.* § 3(b)(1)(B).

¹⁷⁵ *Id.* § 3(b)(2).

¹⁷⁶ See Ana Swanson, *Nike and Coca-Cola Lobby Against Xinjiang Forced Labor Bill*, N.Y. TIMES (Jan. 20, 2021), <https://www.nytimes.com/2020/11/29/business/economy/nike-coca-cola-xinjiang-forced-labor-bill.html> [<https://perma.cc/QJ4B-T78S>].

¹⁷⁷ See Uyghur Forced Labor Prevention Act § 2.

¹⁷⁸ See U.S. DEP’T OF HOMELAND SEC., STRATEGY TO PREVENT THE IMPORTATION OF GOODS MINED, PRODUCED, OR MANUFACTURED WITH FORCED LABOR IN THE PEOPLE’S REPUBLIC OF CHINA: REPORT TO CONGRESS (June 17, 2022), https://www.dhs.gov/sites/default/files/2022-06/22_0617_fletf_uflpa-strategy.pdf [<https://perma.cc/JT9Y-KRGQ>].

¹⁷⁹ See *id.* at v–vi, 34–35.

¹⁸⁰ See *id.* at 9.

¹⁸¹ See *id.*

¹⁸² See *id.* at 9, 40–52.

¹⁸³ See *id.* at 40.

¹⁸⁴ See *id.* at 44.

¹⁸⁵ See *id.* at 41–48.

capable of auditing their supply chains and attesting to the reliability of such an audit.¹⁸⁶ In addition to the enforcement strategy, CBP released Operational Guidance to assist importers in preparing for the implementation of the Act and enforcement of the presumption.¹⁸⁷ The Operational Guidance aims to complement the enforcement strategy and describes how CBP will enforce the presumption.¹⁸⁸

While importers now know that when rebutting the Uyghur Forced Labor Prevention Act they must demonstrate by clear and convincing evidence the lack of forced labor in their supply chains, they are still at a loss as to how they can effectively challenge CBP decisions. The Operational Guidance and the enforcement strategy create greater transparency and provide importers with more information related to the type of data CBP requires to make the necessary determination. As CBP's reasoning behind its decisions are not explicit, the lack of transparency surrounding CBP decision-making creates difficulties for importers when attempting to challenge unfavorable decisions barring their merchandise from entry into the United States.

D. International Guidance

Outside the United States, there has been a greater push toward establishing mandatory supply chain due diligence laws that discourage companies from propagating human rights abuses and ensure fair labor standards in supply chains,¹⁸⁹ which highlights the problems with U.S. enforcement. International guidance may provide clarity regarding how an importer might demonstrate the lack of forced labor in its supply chain, as Congress previously relied on international guidance in this area—Congress intended to implement the same definition of forced labor in Section 307 as included in the ILO Convention No. 29.¹⁹⁰ International organizations including the United

¹⁸⁶ See *id.*

¹⁸⁷ See U.S. CUSTOMS & BORDER PROT., NO. 1793-0522, OPERATIONAL GUIDANCE FOR IMPORTERS (June 13, 2022), https://www.cbp.gov/sites/default/files/assets/documents/2022-Jun/CBP_Guidance_for_Importers_for_UFLPA_13_June_2022.pdf [<https://perma.cc/DNT9-86GF>].

¹⁸⁸ See *id.*

¹⁸⁹ See *EU Commissioner for Justice Commits to Legislation on Mandatory Due Diligence for Companies*, BUS. & HUM. RTS. RES. CTR. (Apr. 30, 2020), <https://www.business-humanrights.org/en/latest-news/eu-commissioner-for-justice-commits-to-legislation-on-mandatory-due-diligence-for-companies/> [<https://perma.cc/6VNY-DQDC>].

¹⁹⁰ The ILO Forced Labour Convention No. 29 defines forced or compulsory labor as “all work or service which is exacted from any person under the threat of a penalty and for which the person has not offered himself or herself voluntarily.” *What is Forced Labour, Modern Slavery and Human Trafficking*, INT’L. LAB. ORG., <https://www.ilo.org/global/topics/forced-labour/definition/lang—en/index.htm> [<https://perma.cc/94EU-Q8Q3>] (quoting

Nations have provided voluntary guidance on due diligence practices to promote corporate responsibility.¹⁹¹ For example, the U.N. Guiding Principles on Business and Human Rights explains that companies should engage in human rights due diligence to identify, prevent, and mitigate adverse human rights impacts.¹⁹² These due diligence practices should include “assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed.”¹⁹³ Yet voluntary human rights due diligence measures are not enough. Only one in three businesses are currently conducting appropriate due diligence measures with regard to their supply chains.¹⁹⁴ The European Union generally has acknowledged the need for a due diligence framework among non-governmental organizations, large and small companies, and business associations.¹⁹⁵ Companies want greater harmonization surrounding corporate due diligence requirements which would clarify legal obligations and establish a level playing field.¹⁹⁶

The European Parliament has expressed concern that not enough is being done to ensure and promote corporate social responsibility.¹⁹⁷ The due diligence measures companies currently have incorporated are not mandated and are insufficient to address corporate social responsibility.¹⁹⁸ Therefore, the

ILO Convention (No. 29) Concerning Forced or Compulsory Labour, June 28, 1930, 39 U.N.T.S. 55). The United States has not ratified ILO Convention No. 29 due to conflicts in domestic law and the practice of use of forced labor in the United States. See CIMINO-ISAACS ET AL., *supra* note 4, at 22; Bade, *supra* note 23, at 8–9.

¹⁹¹ See Off. U.N. High Comm’r for Hum. Rts., Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework, U.N. Doc. HR/PUB/11/04 (Jan. 2012) [hereinafter “Protect, Respect and Remedy” Framework]; Org Econ. Coop. & Dev., OECD Due Diligence Guidance for Responsible Business Conduct (2018), <http://mneguidelines.oecd.org/OECD-Due-Diligence-Guidance-for-Responsible-Business-Conduct.pdf> [<https://perma.cc/X636-CYL3>].

¹⁹² See “Protect, Respect and Remedy” Framework, *supra* note 191, ¶ 15.

¹⁹³ *Id.* ¶ 17.

¹⁹⁴ See Gabriela R. Da Costa et al., *European Union Moves Towards Mandatory Supply Chain Due Diligence: Start Gearing Up for New Directive*, NAT’L L. REV. (Apr. 29, 2021), <https://www.natlawreview.com/article/european-union-moves-towards-mandatory-supply-chain-due-diligence-start-gearing-up-for-new-directive> [<https://perma.cc/V9B3-Z926>].

¹⁹⁵ See *Proposal for a Directive of the European Parliament and of the Council on Corporate Sustainability Due Diligence and amending Directive (EU) 2019/1937*, at 18 n.65–66, COM (2022) 71 final (Feb. 23, 2022) [hereinafter *Proposal for a Directive*].

¹⁹⁶ See *id.* at 18.

¹⁹⁷ See Da Costa et al., *supra* note 194.

¹⁹⁸ See Eur. Comm’n, Directorate-Gen. for Just. and Consumers, Study on due diligence requirements through the supply chain: final report (2020), <https://data.europa.eu/doi/10.2838/39830> [<https://perma.cc/YB5J-CF2D>].

European Union has proposed legislation (“Proposed Directive”) that would create a mandatory human rights due diligence framework as part of the Sustainable Corporate Governance initiative and standardize due diligence laws across Europe.¹⁹⁹ The Proposed Directive would set out substantive due diligence requirements to identify, prevent, mitigate, and account for adverse human rights impacts, which include forced labor.²⁰⁰ Identifying adverse impacts in supply chains becomes easier if more companies exercise due diligence, making more information available on human rights and forced labor, with the ultimate goal of cleaning up the supply chain.²⁰¹

The Proposed Directive lays out due diligence obligations for companies to implement.²⁰² First, companies within the scope of the Proposed Directive would be required to integrate and adopt due diligence policies.²⁰³ These policies must “include a description of the company’s approach to due diligence, of a code of conduct to be followed by the company’s employees and subsidiaries, [and] of the processes put in place to implement due diligence.”²⁰⁴ Under this obligation, companies would have to review and update due diligence policies annually.²⁰⁵ Additionally, companies would be required to take adequate measures to identify actual or potential adverse human rights impacts in their operations and supply chains.²⁰⁶ Companies would need to have a procedure for complaints.²⁰⁷ They also would be required to prevent and mitigate potential adverse human rights impacts.²⁰⁸ Further, companies would have to end, or at least minimize where it is impossible to end, actual adverse human rights impacts.²⁰⁹ Companies would need to evaluate their human rights due diligence efforts to evaluate the effectiveness of their policies and to ensure adverse impacts are identified and remedial measures are implemented.²¹⁰ Finally, companies would also be subjected to a public reporting requirement.²¹¹ These obligations would promote fairer labor standards worldwide and limit the production of merchandise using forced labor by requiring companies to implement human rights policies and publicly share

¹⁹⁹ See *Proposal for a Directive*, *supra* note 195, at 4.

²⁰⁰ See *id.*

²⁰¹ See *id.* at 1–3.

²⁰² See *id.* at 2–4.

²⁰³ See *id.* at 46, 66.

²⁰⁴ *Id.* at 24.

²⁰⁵ See *id.* at 54.

²⁰⁶ See *id.*

²⁰⁷ See *id.* at 58.

²⁰⁸ See *id.* at 35.

²⁰⁹ See *id.* at 56.

²¹⁰ See *id.* at 58.

²¹¹ See *id.* at 59.

their data. The extent of a company's legal obligations to impose and carry out due diligence policies is dependent on its size, risk profile, and business sector and the resources available.²¹²

Here in the United States, importers would benefit from imposing due diligence standards, especially should they need to provide evidence to CBP. Due diligence policies require a company to consistently and diligently monitor labor standards at each production phase and to implement procedures to rectify any human rights abuses. An importer's continued collection of this information would likely comply with CBP's guidance and encourage CBP to revoke or modify a WRO or Finding because of the availability of information. Merely recommending that companies implement due diligence practices has proven ineffective.²¹³ Requiring procedures such as those proposed by the European Union not only would benefit importers but also would make available information regarding human rights practices that would help CBP and other U.S. agencies combat forced labor.

III. Solution

An importer's ability to challenge the conclusion that its merchandise has been manufactured, produced, or mined wholly or in part by forced labor is limited by the lack of transparency in CBP's investigations and guidance. Increased transparency and clarity will help importers demonstrate the lack of forced labor in their supply chains, ensure U.S. consumers' access to merchandise, and enhance enforcement of Section 307. Importers will know exactly how to disprove the suspicion of forced labor in their supply chains, which ultimately will incentivize them to clean up their supply chains and combat forced labor.

This Note's proposed solution is comprised of judicial, executive, and legislative portions which all work together to combat forced labor globally. First, the Federal Circuit should adopt a clear and convincing standard of proof for importers to meet when challenging a WRO or Finding. Second, CBP guidance must be more transparent. Transparency not only benefits importers so that they know what evidence must be offered to CBP but would allow other federal agencies to work in tandem with CBP's efforts in prohibiting forced labor. Finally, Congress should pass due diligence laws that require businesses to adopt standards that further the United States' human rights obligations. This would allow importers to challenge CBP rulings more easily and create greater transparency surrounding labor conditions around the world, leading to improved efficacy of the forced labor prohibition.

²¹² See *id.* at 14.

²¹³ See Da Costa et al., *supra* note 194.

A. Judicial Solution: Clear and Convincing Standard of Proof

The Federal Circuit should adopt a clear and convincing standard of proof that importers must meet to effectively challenge a CBP decision denying an importer's request to revoke or modify a WRO or Finding. In adopting this standard of proof, the Federal Circuit should acknowledge that the current guidance and information CBP provides to importers is insufficient. While the Federal Circuit cannot change CBP's guidance, acknowledging the inadequacy of the current procedures and information may push CBP to update its guidance and increase transparency. Under a clear and convincing standard of proof, importers will be required to demonstrate that it is highly probable that merchandise has not been produced wholly or in part by forced labor.

Though importers will likely protest this standard of proof, as it is a high burden, a lower standard would defeat the purpose of Section 307. Section 307 was initially devised to protect domestic producers so that there were fairer competitive standards (merchandise produced with forced labor would be cheaper than merchandise produced according to fair labor standards);²¹⁴ however, its greater social purpose, as demonstrated by Section 307's recent use, is to eliminate forced labor entirely.²¹⁵ Requiring importers to prove, not just by a preponderance of evidence, but by clear and convincing evidence that their supply chain is clean, is most likely to eliminate forced labor. Congress passed the Uyghur Forced Labor Protection Act creating a presumption of forced labor in merchandise with connections to the Uyghur region in China that may be overcome through clear and convincing evidence.²¹⁶ If clear and convincing evidence is sufficient to overcome such a presumption, this evidentiary standard adopted by the Federal Circuit should also be sufficient to overcome a reasonable suspicion (WRO) or a conclusion of probable cause (Finding) of forced labor present in the supply chain because a presumption is an assumed factual finding, which is stronger than reasonable suspicion or a conclusion of probable cause.

Importers will likely argue that presumption is more difficult to overcome than reasonable suspicion or probable cause and thus a clear and convincing standard is too high. Additionally, a clear and convincing standard of proof would impose a burden, likely costly and time consuming, on importers to collect the relevant information.²¹⁷ However, it would incentivize importers

²¹⁴ See CIMINO-ISAACS ET AL., *supra* note 4, at 3–4.

²¹⁵ See *id.*

²¹⁶ See Uyghur Forced Labor Prevention Act, Pub. L. 117-78 § 2, 135 Stat. 1525–32 (2021).

²¹⁷ See generally Memorandum in Support of Motion for Leave to File a Brief as *Amicus Curiae*, Virtus Nutrition LLC v. United States, No. 1:21-cv-00165 (Ct. Int'l Trade Aug. 26, 2021).

to impose due diligence practices, which not only would promote fair labor standards, but would benefit importers as well.

While burdensome, establishing this clear standard of proof would provide more clarity to importers trying to modify or revoke a ruling from CBP because they would know what standard they must meet. With a defined standard, importers will be able to identify the information necessary to meet the standard of proof with less guidance from CBP, resulting in less back-and-forth between CBP and the importer. This benefits importers, who will have greater knowledge at the outset, resulting in a less burdensome revocation or modification process (less time consuming and less costly), and helps consumers because it allows for the release of merchandise into the United States.

B. Executive Solution: Transparent Guidance

Currently, CBP's reasoning concerning its initial seizures of merchandise at U.S. ports of entry and subsequent WROs and Findings is not transparent. When an importer's shipment is detained, an importer does not know the reasoning behind CBP's decision and therefore struggles to challenge that decision.²¹⁸ Greater transparency should be encouraged to improve enforcement. In its notices to importers, CBP should provide the reasoning for seizing merchandise rather than stating only that the goods are being seized pursuant to Section 307. In providing the reasoning, CBP should outline information that importers must provide to respond to an impending investigation before CBP issues a WRO. Once a WRO or Finding is issued, CBP should outline the evidence which supports CBP's ruling. This transparency would support importers, increase efficiency throughout the WRO process, and promote greater communication and collaboration with other federal agencies in supporting efforts to combat forced labor.

CBP's guidance cautions against document dumps;²¹⁹ however, providing specific information to importers about what information is required would avoid document dumps. In determining whether to modify or revoke a WRO or Finding, CBP needs to conclude that the supply chain is free from any connection to forced labor or that the importer has addressed and remedied the forced labor indicators. In addition to requiring signed certificates of origin, signed statements of evidence, and signed statements from the ultimate consignee, CBP should require detailed supply chain maps, which are signed at each stage of production, and the findings of regular independent audits. A detailed supply chain map would include information as to where (geographic location and facility) each stage of the production occurred including the

²¹⁸ See *Trade Compliance Flash: First Court Challenge to CBP Enforcement of Withhold Release Order*, *supra* note 134.

²¹⁹ See SUBMITTING PROOF OF ADMISSIBILITY, *supra* note 122.

type of labor used. The labor characteristics should be supported by evidence such as images of working and living conditions and pay stubs. Independent audits must occur annually. The findings must outline the methods of investigation and identify the types of labor used and any remedial actions the importer took because of the previous audit. While it may be difficult to require specific documentation for all importers when the investigations are fact specific, CBP could be more transparent in the types of evidence needed when issuing WROs and Findings to importers. Even though this still leaves the power in the hands of CBP, who can continuously request and reject proof of the types of labor and source of materials provided, the importer will be in a better position to demonstrate compliance and challenge CBP decisions.

C. Legislative Solution: Supply Chain Due Diligence Laws

Due diligence is costly for companies and therefore importers do not voluntarily collect detailed information regarding their supply chains, which in turn means importers do not have the type of information CBP requests when an importer attempts to revoke or modify a WRO or Finding on hand, creating difficulties for importers attempting to import goods into the United States.²²⁰ Should CBP amend its guidance, as suggested above, to include results from independent audits and detailed supply chain maps, importers would likely be disadvantaged and enforcement of the prohibition on forced labor would be weakened. The E.U. study reveals that guidance and voluntary measures are insufficient, and corporations will not take the necessary measures to enforce labor standards in their supply chains unless mandated.²²¹ Mandating due diligence obligations would require importers to collect and analyze the information CBP seeks regardless of CBP's actions towards the importer—an importer will have detailed records about its supply chain irrespective of whether CBP seizes or detains the merchandise. These due diligence obligations, which would mimic the E.U. Proposed Directive, would require importers to comply with Section 307 because importers would consistently and thoroughly track their supply chains, whereas clear guidance from CBP would only encourage and not require these actions. Ultimately, further legislative support, along with clearer CBP guidance, is needed to fully realize effective enforcement of Section 307.

Congress should follow the European Union's lead and implement supply chain due diligence laws. U.S. lawmakers could use the E.U. Proposed Directive as a framework for drafting effective legislation. Legislation that

²²⁰ See, e.g., Drew Calvert, *The Costs and Benefits of Supply Chain Transparency*, INSIGHTS BY STANFORD BUSINESS, (Nov. 6, 2020), <https://www.gsb.stanford.edu/insights/costs-benefits-supply-chain-transparency> [<https://perma.cc/F9EW-DN88>].

²²¹ See Da Costa et al., *supra* note 194.

requires importers to implement due diligence procedures would serve the purpose of Section 307 and make it easier for them to challenge a WRO or Finding. Due diligence laws, complemented by clear guidance from CBP, would also benefit other federal agencies enforcing Section 307 and other forced labor provisions. Under a due diligence framework, companies would be obligated to identify and evaluate every stage of their supply chains including facilities they contract with and ascertain the raw materials and types of labor used. An effective due diligence framework should include not only the classification of materials and labor, but also force companies to identify potential issues and take steps to mitigate them. Additionally, companies should track implementation of their efforts to prevent forced labor, address any issues, and publish their efforts. The extent of a company's obligations should depend on its size, resources, industry sector, and risk profile. Therefore, larger companies would have a higher burden, creating a fairer competitive market.

The United States should adopt a due diligence framework that imposes a responsible business practice on companies. Consistent due diligence practices alleviate some of the frustration and concern related to modifying or revoking a WRO or Finding because the information necessary to show a clean supply chain would be more readily available at the start of the time-barred petition period. Further, consistent evaluation of labor standards globally gets at the heart of the purpose of Section 307—to eliminate forced labor. With greater access to information, U.S. agencies can implement policies to further their efforts and more successfully protect U.S. persons and markets. Information on labor practices is necessary to effectively enforce Section 307's prohibition on forced labor.

Conclusion

Without clarifying CBP's expectations regarding enforcement on the prohibition of forced labor, the power of Section 307 will be diluted. Importers will struggle to demonstrate conformity with Section 307 and will continue to be disincentivized from complying with fair labor standards. Other federal agencies will continue inefficient policies to combat forced labor generally. Greater transparency and increased information will benefit all actors—importers will clean up their supply chains, CBP will have more efficient and effective enforcement, and federal agencies will work together in preventing forced labor. Without a clear and convincing evidentiary standard of proof, transparency from CBP, and required due diligence practices, modern slavery will continue to persist.

Cannabis and Marijuana Patents: Is Blunt Enforcement Too High a Proposition?

Philip Russell III*

Introduction

In 2014, Washington State and Colorado voters passed referendums legalizing adult marijuana use.¹ These voter-approved measures created the first state-level recreational marijuana regimes and directly contributed to the federal-state dichotomy on marijuana policy that currently exists.² Though Washington State's and Colorado's referendums were the first to expand legal marijuana use beyond medical use to recreational use, they were not the last.³ Today, eighteen states and the District of Columbia have legalized recreational marijuana use and another eighteen have legalized medical marijuana use.⁴

The wave of marijuana legalization and decriminalization both domestically and internationally has led to a rapid expansion of the legal marijuana industry that amassed \$17.5 billion in 2020 and is projected to reach \$43 billion by 2025.⁵ Marijuana has come a long way as the days of long-haired

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¹ See 2013 Wash. Sess. Laws 29; COLO. CONST. art. XVIII, § 16.

² See 2013 Wash. Sess. Laws 29; COLO. CONST. art. XVIII, § 16; Controlled Substances Act, 21 U.S.C. § 812 (2018).

³ See Claire Hansen et al., *Where is Marijuana Legal? A Guide to Marijuana Legalization*, U.S. NEWS (July 27, 2022), <https://www.usnews.com/news/best-states/articles/where-is-marijuana-legal-a-guide-to-marijuana-legalization>.

⁴ See *id.* This data shows how many states now have marijuana policy directly conflicting with federal policy. See *id.*

⁵ See Will Yakowicz, *U.S. Cannabis Sales Hit Record \$17.5 Billion as Americans Consume More Marijuana Than Ever Before*, FORBES (Mar. 3, 2021, 3:43 PM), <https://www.forbes.com/sites/willyakowicz/2021/03/03/us-cannabis-sales-hit-record-175-billion-as-americans-consume-more-marijuana-than-ever-before/?sh=12f4c5972bcf> [<https://perma.cc/4QLB-35Z3>]; Iris Dorbian, *Legal Cannabis Market Projected to Rack Up \$43 Billion by 2025*, FORBES (June 18, 2021, 8:20 AM), <https://www.forbes.com/sites/irisdorbian/2021/06/18/legal-cannabis-market-projected-to-rack-up-43-billion-by-2025-says-new-study/?sh=1b54d50536b4> [<https://perma.cc/7E3U-6TKG>]. The large size of the marijuana market and its projected

hippies fade and corporations, Wall Street investors, and traders enter the market. Marijuana industry leaders like Aphria, Canopy Growth, Tilray, Aurora Cannabis, Cronos Group, and GW Pharmaceuticals are only some of the cannabis companies that now trade on American stock exchanges.⁶ Altria, the largest American tobacco producer, purchased a 45% stake in Cronos Group and filed patents for marijuana vaporizer technology.⁷ This continued rapid expansion could lead the industry to heights similar to the heyday of the 1960s tobacco industry.⁸ Despite these strides in state legalization and industry expansion, federal law has not changed: marijuana is still classified and outlawed as a Schedule 1 narcotic under the Controlled Substances Act (“CSA”).⁹ As a Schedule 1 narcotic, marijuana is classified the same as heroin and MDMA and is not approved for medical treatment or use at the federal level in the United States.¹⁰ This creates unique problems for the industry in protecting future marijuana and cannabis innovation and intellectual property.¹¹

As in any other industry, intellectual property and patents play an important role in the cannabis and marijuana industry.¹² The United States Patent and Trademark Office (“USPTO”) began issuing marijuana and cannabis

growth demonstrate it is a lucrative market that will continue to attract new investments and entrepreneurs. *See id.*

⁶ See James V. Baker, *Cannabis Stocks Ranked From Cheapest to Most Expensive*, SEEKING ALPHA (Oct. 1, 2020, 8:00 AM), <https://seekingalpha.com/article/4377118-cannabis-stocks-ranked-from-cheapest-to-expensive> [<https://perma.cc/4DMP-LJH5>]. Marijuana stocks trading on Canadian and American stock exchanges lend legitimacy to the industry as these companies need to comply with SEC and exchange rules. *See id.* Their presence on exchanges shows that large companies and sophisticated businesspeople are investing in the marijuana industry. *See id.*

⁷ See Chris Roberts, *Tobacco Giant Altria is Securing Technology in New Frontier: Marijuana*, FORBES (Oct. 2, 2020, 6:30 AM), <https://www.forbes.com/sites/chrisroberts/2020/10/02/tobacco-giant-altria-is-securing-technology-in-new-frontier-marijuana/?sh=336627fd14af> [<https://perma.cc/9WB5-YYEA>].

⁸ See K. Michael Cummings & Robert N. Proctor, *The Changing Public Image of Smoking in the United States: 1964-2014*, 23 CANCER, EPIDEMIOLOGY, BIOMARKERS & PREVENTION 32–33 (2014).

⁹ See 21 U.S.C. § 812; U.S. DEP’T OF JUST. & DRUG ENF’T ADMIN., DRUG FACT SHEET: CANNABIS (Apr. 2020), https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf [<https://perma.cc/664P-VT8T>] [hereinafter DRUG FACT SHEET]. Official federal policy is highlighted by the CSA and DEA policy, highlighting the federal side of the federal-state dichotomy of marijuana policy. *See id.*

¹⁰ See 21 U.S.C. § 812.

¹¹ See discussion *infra* Section II.B.

¹² See William J. McNichol Jr., *The New Highwayman: Enforcement of U.S. Patents on Cannabis Products*, 101 J. PAT. & TRADEMARK OFF. SOC’Y 24, 24 (2019).

utility patents regularly in the 2000s, even issuing a marijuana patent in 2000 to the federal government.¹³ The USPTO has also issued numerous marijuana plant patents since 2016.¹⁴ Although marijuana and cannabis patents have been issued for over twenty years, only two patent infringement suits concerning marijuana patents have been brought in federal district courts and neither were fully litigated before a jury.¹⁵ One was dismissed due to the plaintiff's bankruptcy and the other is scheduled for appellate review of the district court's claim construction ruling that led to dismissal.¹⁶ This lack of case law leaves important issues involving marijuana patent infringement suits unresolved: (1) whether federal courts should even hear marijuana patent infringement suits or dismiss them outright; and (2) whether damages or injunctions can be awarded if infringement is found.¹⁷ Many practitioners and academics who have studied and analyzed patent and federal legal issues involving marijuana and cannabis patents believe that the illegality doctrine,

¹³ See *Cannabinoids as Antioxidants and Neuroprotectants*, U.S. Patent No. 6,630,507 (filed Apr. 21, 1999) (issued Oct. 7, 2003). The U.S. government was issued a cannabis patent that is still in effect today. See *id.* This demonstrates that even the Federal Government has an interest in enforcing its own exclusive rights over a cannabis patent while cannabis is illegal under the CSA.

¹⁴ See *Cannabis Plant Named 'Ecuadorian Sativa'*, U.S. Patent No. PP27,475 (filed Mar. 13, 2010) (issued Dec. 20, 2016); Tamara Fraizer, *Twelve Cannabis Plant Patents and Counting*, 12 NAT'L L. REV. (2021), <https://www.natlawreview.com/article/twelve-cannabis-plant-patents-and-counting> [<https://perma.cc/VTB7-URFV>].

¹⁵ Holds true as of October 2022. See *United Cannabis Corp. v. Pure Hemp Collective, Inc.*, No. 1:18-cv-01922, 2021 WL 6063595 (D. Colo. Dec. 22, 2021); Complaint for Patent Infringement and Demand for Jury Trial, *United Cannabis Corp. v. Pure Hemp Collective Inc.*, No. 1:18-cv-01922 (D. Colo. Jul. 30, 2018); Stipulation of Dismissal, *United Cannabis Corp. v. Pure Hemp Collective Inc.*, No. 1:18-cv-01922 (D. Colo. Mar. 31, 2021); Order Denying Defendant's Early Motion for Partial Summary Judgment at 1, *United Cannabis Corp.*, No. 1:18-cv-01922 (Apr. 17, 2019); Complaint for Patent Infringement, *Canopy Growth Corp. v. GW Pharms. PLC*, No. 6:20-cv-1180 (W.D. Tex. Dec. 22, 2020); Final Judgment at 4, *Canopy Growth Corp. v. GW Pharms. PLC*, No. 6:20-cv-1180 (W.D. Tex. Feb. 25, 2022).

¹⁶ See Stipulation of Dismissal, *supra* note 15; Plaintiff Canopy Growth Corporation's Notice of Appeal at 1, *Canopy Growth*, No. 6:20-cv-01180 (W.D. Tex. Mar. 24, 2022).

¹⁷ See Karen J. Bernstein, *Counseling Marijuana Clients on Intellectual Property: Protection and Enforcement*, 90 N.Y. ST. BAR ASS'N J. 20 (2018); McNichol, *supra* note 12, at 28–29; Keith A. Barritt et al., *IP and Cannabis: The Current Landscape*, FISH & RICHARDSON (Dec. 2, 2020), <https://www.fr.com/ip-cannabis-current-landscape/> [<https://perma.cc/7FGN-T29J>]; Daniel Pereira & Alec Royka, *Why Cannabis Patent Enforcement Is in the Weeds*, OBLON (Jul. 8, 2019), https://www.oblon.com/A11960/assets/files/News/DPereria_Why%20Cannabis%20Patent%20Enforcement%20is%20in%20the%20Weeds_7.8.19.pdf [<https://perma.cc/DH88-YG7F>].

a legal doctrine that prohibits courts from rewarding or aiding illegal activity, would prevent federal courts from enforcing patent rights in marijuana patent infringement suits.¹⁸ Proponents of the illegality doctrine argue that courts will be averse to enforcing the rights of a marijuana patentee to further a marijuana enterprise that is deemed criminal at the federal level.¹⁹

This analysis is wrong. A patent creates an exclusive right, and by enforcing this right, courts can prevent activity prohibited under the CSA by providing equitable relief through injunctions.²⁰ Further, many patentees are non-practicing entities who do not make or sell products but rather perform research, such as universities.²¹ Non-practicing entities taking part in research do not violate the CSA; however, those who infringe their cannabis and marijuana patents likely do.²² Non-practicing entities create the unique case in which non-enforcement of a patent would enable infringers to continue violating the CSA.²³ Additionally, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”), which hears appeals of patent infringement cases,²⁴ has stated that it is not the role of patent law to implement the states’ police powers—including the enforcement of state narcotics law.²⁵ That is the job of the Drug Enforcement Administration (“DEA”) and the U.S. Department of Justice (“DOJ”).²⁶ Finally, the federal government has all but abandoned criminal marijuana enforcement in states that have legalized marijuana use even though such use is a blatant violation of the CSA.²⁷

¹⁸ See generally Bernstein, *supra* note 17; McNichol, *supra* note 12, at 46, 48; Barritt et al., *supra* note 17, at 1, 4; Pereira & Royka, *supra* note 17.

¹⁹ See McNichol, *supra* note 12, at 48.

²⁰ See U.S. CONST. art I, § 8; 35 U.S.C. § 283 (2018).

²¹ See Rob Cerwinski et al., *Insight: Why the Illegality Doctrine Shouldn't Apply to Cannabis Patents*, BLOOMBERG L. (Jan. 17, 2021, 4:01 AM), <https://news.bloomberglaw.com/ip-law/insight-why-the-illegality-doctrine-shouldnt-apply-to-cannabis-patents> [<https://perma.cc/9ZHY-YAWM>].

²² See *id.*

²³ See discussion *infra* Section II.F.

²⁴ See *Just the Facts: Intellectual Property Cases—Patent, Copyright, and Trademark*, U.S. COURTS (Feb. 13, 2020), <https://www.uscourts.gov/news/2020/02/13/just-facts-intellectual-property-cases-patent-copyright-and-trademark> [<https://perma.cc/7G6T-ZDNZ>] (“Patent appeals that originate in the U.S. district courts, including counterclaims, are exclusively the jurisdiction of the United States Court of Appeals for the Federal Circuit . . .”) [hereinafter *Just the Facts*].

²⁵ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999).

²⁶ See 21 U.S.C. § 812; DRUG FACT SHEET, *supra* note 9.

²⁷ See James M. Cole, U.S. Dep’t of Just., *Guidance Regarding Marijuana Enforcement*, 26 FED. SENT’G REP. 217 (Apr. 2014); Responses to Questions for the Record to Judge Merrick Garland, Nominee to be United States Attorney General, at 24 (Feb. 28, 2021), <https://>

The USPTO and courts should look to 35 U.S.C. § 271,²⁸ the patent infringement statute, and follow its guidance to resolve these issues.²⁹ Pursuant to the statute, courts should treat patent infringement of marijuana patents as they treat patent infringement of any other art, especially since § 271 makes no distinction between the potential legal or illegal nature of the patented activity when determining infringement.³⁰ This would help eliminate current confusion and unpredictability surrounding intellectual property for entities making investments in this growing industry.³¹ Doing so will also prevent lawlessness and the erosion of patents in other arts that will inevitably result from refusal to respect patents in the marijuana art.

This Note examines the background of marijuana's current legal status under state and federal laws, how these conflicting laws create uncertainty that is exacerbated by federal inconsistencies in marijuana enforcement under the CSA, and federal court treatment of civil cases involving marijuana and marijuana patents. Part I provides a background of cannabis and marijuana patents under patent law. In Part II, this Note will analyze how patent infringement remedies may affect judicial decisions in cannabis and marijuana patent infringement cases and how past Federal Circuit cases hint at future case treatment. It will show how a refusal to enforce cannabis and marijuana patents will lead to unfair and absurd results, especially in light of how marijuana-related civil cases and the two federal infringement suits were handled in federal courts. Finally, in Part III, this Note will examine how the Federal Circuit can provide clarity by ensuring cannabis and marijuana patentees can enforce their rights against infringers and that alternatives lead to less-than-optimal results.

I. Background: Federal and State Legal Status of Marijuana

A. Federal Legal Marijuana Landscape

The cannabis plant includes the compounds tetrahydrocannabinol ("THC") and cannabidiol ("CBD"), among other compounds.³² THC is the mind-altering compound that produces marijuana's psychoactive effect, whereas

www.judiciary.senate.gov/imo/media/doc/QFR%20Responses%202-28.pdf [<https://perma.cc/6KTP-PMH3>].

²⁸ 35 U.S.C. § 271 (2018).

²⁹ *See id.*

³⁰ *See id.*

³¹ *See* Dariush Adli, *Intellectual Property Guidance for Cannabis Products and Services*, 43 L.A. LAW. 10, 10 (2020).

³² *See* Mary Jo DiLonardo, *CBD vs. THC: What's the Difference?*, WEBMD (Dec. 15, 2021), <https://www.webmd.com/pain-management/cbd-thc-difference> [<https://perma.cc/N9TK-FB6M>].

CBD does not produce this effect.³³ Cannabis plants with greater than 0.3% THC are classified as marijuana, and cannabis plants containing 0.3% or less THC are legally classified as hemp.³⁴ Hemp is useful because it typically has a higher concentration of CBD than marijuana.³⁵ The Agricultural Improvement Act of 2018,³⁶ commonly known as the 2018 Farm Bill, made significant changes to federal policy regarding cannabis by legalizing the production of hemp and its extracts like CBD.³⁷ While the 2018 Farm Bill did not change the classification of marijuana as a Schedule 1 narcotic under the CSA, it did legalize and distinguish hemp from marijuana based on the underlying cannabis plant's percentage levels of THC.³⁸

Even though many states have decriminalized marijuana, marijuana and marijuana-derived CBD remains illegal under the CSA.³⁹ CBD, especially hemp-derived CBD, has gained recent popularity with its proponents touting its relief for anxiety and depression without the high from THC.⁴⁰ These claims were bolstered by the Food and Drug Administration's ("FDA") approval of GW Pharmaceuticals' Epidiolex, a CBD extract for treatment of epileptic seizures.⁴¹ However, the contrasting state legalization and federal classification of marijuana as a Schedule 1 narcotic have provided opportunities for criminal groups to take advantage of state legal regimes in attempt to avoid federal enforcement.⁴²

B. The Federal-State Marijuana Legal Dichotomy

A major dichotomy in the black letter law between states and the federal government has existed since marijuana was first legalized in Washington State and Colorado.⁴³ Numerous states followed Colorado and Washington State's lead by legalizing recreational marijuana, as recreational marijuana is

³³ See 7 U.S.C. § 1639o (2018).

³⁴ See *id.* THC percentage is calculated on a dry weight basis. See *id.*

³⁵ See *id.*; DiLonardo, *supra* note 32.

³⁶ Agricultural Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

³⁷ See 7 U.S.C. § 1639o (2018).

³⁸ See *id.*; 21 U.S.C. § 812 (2018) (categorizing Tetrahydrocannabinol, a main compound of marijuana, as a prohibited narcotic).

³⁹ See 21 U.S.C. § 812 (2018).

⁴⁰ See Dawn MacKeen, *Extracting Facts Can be Difficult*, N.Y. TIMES, Oct. 20, 2019, at F11.

⁴¹ See *id.*

⁴² See Paul Demko, *Inside the Rise—and Surprising Crackdown—of the Country's Hottest Weed Market*, POLITICO, (Nov. 12, 2021, 4:30 AM), <https://www.politico.com/news/magazine/2021/11/12/oklahoma-marijuana-laws-520311> [<https://perma.cc/C6EY-UDR6>].

⁴³ See 2013 Wash. Sess. Laws 29; COLO. CONST. art. XVIII, § 16; 21 U.S.C. § 812 (2018).

now legal in eighteen states, Washington, D.C., and Guam.⁴⁴ Even though many states now allow and regulate marijuana industries, marijuana industry actors who comply with their state's marijuana laws and regulations are still technically in violation of the CSA.⁴⁵ This quirk of violating federal law by following state law is the result of the federal government's continued classification of marijuana as a Schedule 1 narcotic.⁴⁶ Yet, the federal government has not criminally pursued individuals or entities in compliance with state legal marijuana industries, instead preferring to criminally pursue those who violate both federal and state marijuana laws.⁴⁷

C. High Time for Action

Enforcement of cannabis and marijuana patents is a timely issue as state and foreign national legalization has resulted in the rapid expansion of the marijuana industry.⁴⁸ The American marijuana market not only generates billions of dollars in revenue, but has also seen massive growth, such as the 46% growth from 2019 to 2020, which makes the industry lucrative and attractive for investors.⁴⁹ This growth and profitability is leading established American companies to increase investment into the marijuana industry.⁵⁰ However, marijuana's classification as a Schedule 1 narcotic, coupled with its federal prohibition, prevents marijuana businesses from accessing federally regulated banking or financial systems.⁵¹

Congress has already begun working to eliminate this financial barrier, which effectively locks industry entities out of the banking system and Wall Street investment money.⁵² For example, H.R. 1595, more commonly known as the SAFE Banking Act of 2019, received bipartisan support in the House of Representatives and was subsequently passed in the House during the

⁴⁴ See Hansen et al., *supra* note 3.

⁴⁵ See 21 U.S.C. § 812 (2018).

⁴⁶ See *id.*

⁴⁷ See Cole, *supra* note 27.

⁴⁸ See Yakowicz, *supra* note 5.

⁴⁹ See *id.*

⁵⁰ See Roberts, *supra* note 7.

⁵¹ See Shariq Khan, *U.S. Pot Sellers Stash Cash as Banks Leave Them High and Dry*, REUTERS (May 24, 2021, 2:17 AM), <https://www.reuters.com/world/us/us-pot-sellers-stash-cash-banks-leave-them-high-dry-2021-05-24/> [<https://perma.cc/MXV9-CE4M>].

⁵² See SAFE Banking Act of 2019, H.R. 1595, 116th Cong. (as passed by House, Sept. 26, 2019); SAFE Banking Act of 2021, H.R. 1996, 117th Cong. (as passed by House, Apr. 19, 2021); S. 1200, 116th Cong. (as referred to Committee on Banking, Housing, and Urban Affairs, Apr. 11, 2019); SAFE Banking Act of 2021, S. 910 117th Cong. (as referred to Committee on Banking, Housing, and Urban Affairs, Mar. 23, 2021).

following Congress in 2021.⁵³ The bill is now pending before the Senate and had the bipartisan support of thirty-four co-sponsors in 2019, expanding to forty-two in 2022.⁵⁴ If the Act becomes law, it would allow banks to accept funds from the cannabis industry, easing a major barrier to the industry by making banking services accessible to industry players.⁵⁵

Historically, the U.S. federal government invested billions of dollars in researching the negative effects and medical efficacy of marijuana.⁵⁶ Now, private companies in the marijuana industry are also making sizable research and development (“R&D”) investments driven by the profit these newly legalized products provide.⁵⁷ This is demonstrated by Canopy Growth’s R&D investments of \$57.5 million in the 2021 fiscal year.⁵⁸ Many marijuana industry leaders such as Canopy Growth already trade on the NASDAQ, and if they are not already in the American market, they are preparing to enter into it.⁵⁹ Established tobacco companies such as Altria are making investments in the marijuana and cannabis industry as well.⁶⁰ With major corporate players entering the field, intellectual property will likely become a legal battleground just as the recent tobacco industry competition over heated tobacco sticks and vaporizer technology led to a massive increase in patent lawsuits.⁶¹

D. Federal Enforcement and Non-Enforcement

Federal non-enforcement of the marijuana prohibition began during the Obama Administration with the Cole Memo, which instructed DOJ attorneys to de-emphasize federal marijuana enforcement in states that legalized

⁵³ See H.R. 1595; H.R. 1996. Even in the more partisan House of Representatives, both H.R. 1595 and H.R. 1996 had bipartisan co-sponsors. See H.R. 1595; H.R. 1996.

⁵⁴ See S. 1200; S. 910. There is bipartisan and growing support in the more deliberative Senate for opening the banking system to marijuana businesses; the 2021 Senate bill has eight more sponsors than the 2019 Senate bill. See S. 1200; S. 910.

⁵⁵ See H.R. 1996; S. 910.

⁵⁶ See National Institutes of Health, *Estimates of Funding for Various Research, Conditions, and Disease Categories*, NIH RESEARCH PORTFOLIO ONLINE REPORTING TOOLS (May 16, 2021), <https://report.nih.gov/funding/categorical-spending#/> [<https://perma.cc/2XC3-CJSS>].

⁵⁷ See generally Canopy Growth Corp., *Fiscal Year 2021 Annual Report* (July 30, 2021), https://www.canopygrowth.com/wp-content/uploads/2021/07/CanopyGrowth_AnnualReport_2021_7_30-1.pdf [<https://perma.cc/7DMK-FHFV>].

⁵⁸ See *id.* at F-23.

⁵⁹ See *id.* at 20; see also Baker, *supra* note 6.

⁶⁰ See Roberts, *supra* note 7.

⁶¹ See Carol Ryan, Opinion, *Tobacco Industry Back in Court*, WALL ST. J., Oct. 13, 2021, at B.14.

and regulated marijuana.⁶² The Cole Memo was rescinded during the Trump Administration by Attorney General Sessions, which prompted worries of aggressive federal enforcement against state legal marijuana industries.⁶³ Yet, that never happened; even after the rescission of the Cole Memo, marijuana prosecutions were on the decline in 2018.⁶⁴ Although the Cole Memo has not been reinstated, and a new memo has not been issued, the Biden Administration has signaled it likely will not pursue criminal cases against parties complying with state marijuana laws.⁶⁵ During his confirmation hearings, Attorney General Garland stated, “I do not think it is the best use of the Department’s limited resources to pursue prosecutions of those who are complying with the laws in states that have legalized and are effectively regulating marijuana.”⁶⁶ Attorney General Garland further declared, “There are no end runs around the state laws by criminal enterprises,” signaling federal enforcement would target those who violate both state and federal marijuana law.⁶⁷ However, the federal government has tools beyond criminal prosecution that it can use to apply pressure to enforce its marijuana policy under the CSA.

1. Federal Enforcement Through the Bankruptcy System

Although the federal government has neither criminally prosecuted state marijuana industries, nor the actors within them, the federal government employs other aspects of federal law against them.⁶⁸ Congress has plenary

⁶² See Cole, *supra* note 27, at 218. The Guidance Regarding Marijuana Enforcement laid out policy regarding federal non-enforcement of marijuana under the CSA during the Obama Administration. See *id.*

⁶³ See OFF. OF THE ATT’Y GEN., MEMORANDUM FOR ALL UNITED STATES ATTORNEYS, MARIJUANA ENFORCEMENT (Jan. 4, 2018).

⁶⁴ Then-Attorney General Sessions rescinded the Cole Memo but concerns that federal marijuana enforcement would target state-authorized industries were overblown given that federal marijuana cases did not spike. See *id.*; see also CHIEF JUSTICE JOHN G. ROBERTS, 2018 YEAR-END REPORT ON THE FEDERAL JUDICIARY 14 (Dec. 31, 2018), <https://www.supremecourt.gov/publicinfo/year-end/2018year-endreport.pdf> [<https://perma.cc/UB8H-7ACP>].

⁶⁵ See Responses to Questions for the Record to Judge Merrick Garland, *supra* note 27, at 24.

⁶⁶ Responses to Questions for the Record to Judge Merrick Garland, *supra* note 27, at 24. Attorney General Garland’s written answers during his nomination hearings provide insight into how the Department of Justice will handle marijuana prosecutions related to legal state marijuana industries under his leadership.

⁶⁷ *Id.*

⁶⁸ See U.S. CONST. art I, § 8; Clifford J. White III & John Sheahan, *Why Marijuana Assets May Not Be Administered in Bankruptcy*, 36 AM. BANKR. INST. J. 34, 35 (Dec. 2017). The federal government uses Congress’s interstate commerce power and the federal bankruptcy system to limit the marijuana industry even in states where it is legal. See *id.*; U.S. CONST. art I, § 8, cl. 3.

power over interstate commerce, including banning items such as marijuana from interstate commerce, thereby preventing marijuana businesses from crossing state lines even when the receiving states have decriminalized or legalized marijuana.⁶⁹ The bankruptcy system is another federal entity that does not make exceptions for legal state marijuana businesses.⁷⁰ The United States Trustee Program (“USTP”) has moved to dismiss marijuana-related bankruptcies as inconsistent with federal law.⁷¹ The USTP’s official stance is that debtors must give up their marijuana assets and may not use the bankruptcy system to rehabilitate marijuana businesses because doing so violates federal law.⁷² The USTP distinguishes marijuana bankruptcy from other acts, such as Ponzi schemes, because unlike crimes where the underlying fraud or illegal activity has ceased, a marijuana business continues to violate federal law by selling or producing marijuana.⁷³ The USTP refuses to lend the aid of the bankruptcy system to help parties that profit from continued violation of the CSA.⁷⁴ Since the USTP believes it improper to extend federal benefits to businesses that simultaneously violate federal law, it maintains its stance against enabling marijuana debtors to successfully emerge from bankruptcy due to their continued violation of the CSA.⁷⁵

2. Federal Courts and Marijuana Civil Cases

Courts have taken notice of the inconsistency of these “conflicting signals” coming from the federal government regarding its “nominal” marijuana prohibition.⁷⁶ In *Green Earth Wellness Center, LLC v. Atain Specialty Insurance Co.*,⁷⁷ the United States District Court for the District of Colorado refused

⁶⁹ See *United States v. Carolene Prods. Co.*, 304 U.S. 144, 147 (1938) (finding that Congress’s power over interstate commerce is only limited by the Constitution and includes the power to prohibit items from interstate commerce).

⁷⁰ See *White & Sheahan*, *supra* note 68.

⁷¹ See *id.*

⁷² See *id.*

⁷³ See *id.* The USTP distinguishes bankruptcy involving illicit proceeds from criminal activity from marijuana business; its position is that the bankruptcy proceeding comes after the fraud and illegal activity has happened and contrasts to a marijuana bankruptcy where a dispensary may try to continue its business throughout the proceedings and in the process violates the CSA. See *id.*

⁷⁴ See *id.*

⁷⁵ See *id.*

⁷⁶ *Green Earth Wellness Ctr., LLC v. Atain Specialty Ins. Co.*, 163 F. Supp. 3d 821, 832 (D. Colo. 2016) (deciding the merits of the claims rather than dismissing under the illegality doctrine when a marijuana dispensary sued an insurance carrier over contract dispute involving commercial insurance).

⁷⁷ 163 F. Supp. 3d 821 (D. Colo. 2016).

to grant summary judgement and invalidate an insurance policy on the basis that the insured was a medical marijuana dispensary.⁷⁸ Atain issued Green Earth Wellness, a Colorado medical marijuana dispensary, commercial insurance.⁷⁹ Green Earth Wellness made insurance claims when an area wildfire caused smoke damage to marijuana plants and for damage resulting from a break-in.⁸⁰ Atain denied both claims and Green Earth Wellness sued for breach of contract.⁸¹

Instead of dismissing the case on public policy grounds, the court relied on traditional contract principles, stating that a judgement would be “based on Atain’s failure to honor its contractual promises.”⁸² The court cited an earlier case, *Tracy v. USAA Casualty Insurance Co.*,⁸³ in which the United States District Court for the District of Hawaii found the CSA trumped an insurance policy because the contract was contrary to federal law and policy.⁸⁴ The court in *Green Earth Wellness* refused to follow *Tracy* due to inconsistent federal policy surrounding legal state marijuana.⁸⁵ This was significant because *Tracy* was the only other federal case to address insurance policy claims for marijuana plants.⁸⁶

The United States District Court for the Western District of Missouri heard and decided another marijuana-related case on the merits in *Toigo v. Department of Health and Senior Services*.⁸⁷ Mark Toigo sued the Missouri Department of Health and Senior Services (“DHSS”) claiming the Missouri residency requirements for medical marijuana business ownership violated the Dormant Commerce Clause.⁸⁸ The court granted a preliminary injunction against Missouri’s residency requirement to own or operate cannabis businesses, finding Mr. Toigo established the need for an injunction.⁸⁹ The court mentioned the illegal status of marijuana in Missouri and at the federal level in its order but did not dismiss the case *sua sponte*.⁹⁰ Instead, the court proceeded to hear the case on the merits and issued a permanent injunction

⁷⁸ See *id.* at 835, 837.

⁷⁹ See *id.* at 823.

⁸⁰ See *id.* at 823–24.

⁸¹ See *id.* at 824.

⁸² *Id.* at 834.

⁸³ No. 11-00487, 2012 U.S. Dist. LEXIS 35913 (D. Haw. Mar. 16, 2012).

⁸⁴ See *id.* at *38–39.

⁸⁵ See *Green Earth Wellness*, 163 F. Supp. 3d at 835.

⁸⁶ See *id.*; see also *Tracy*, 2012 U.S. Dist. LEXIS 35913.

⁸⁷ 549 F. Supp. 3d 985 (W.D. Mo. 2021).

⁸⁸ See *id.* at 988.

⁸⁹ See *id.* at 996.

⁹⁰ See *id.* at 991.

prohibiting the Missouri DHSS from enforcing the residency requirements, noting that the underlying facts had not changed since the earlier ruling.⁹¹

E. Patent Law Background

The authority to issue patents derives from Article I of the Constitution, from which Congress passed one of its first acts, the Patent Act of 1790.⁹² The modern patent statute, 35 U.S.C. § 101,⁹³ states an inventor may obtain a patent for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁹⁴ Nothing in the constitutional or statutory patent framework prohibits a marijuana or marijuana-related patent.⁹⁵ In *Diamond v. Chakrabarty*,⁹⁶ the Supreme Court affirmed that a composition of matter is patentable.⁹⁷ Adhering to the Court’s reasoning in *Chakrabarty*, it follows that man-made marijuana plants and marijuana-related inventions that are compositions of matter, and not naturally occurring, are patentable.⁹⁸ The USPTO follows this reasoning as it not only issues design and utility marijuana patents, but also issues marijuana plant patents.⁹⁹ Plant patents are issued to anyone who invents or discovers and asexually reproduces a new type of plant.¹⁰⁰ Utility, design, and plant patents can all apply to the marijuana industry.¹⁰¹

1. The USPTO Issues Cannabis and Marijuana Patents

Against this backdrop, the USPTO has issued cannabis and marijuana plant, design, and utility patents.¹⁰² Nothing in § 101 prohibits a patent for marijuana or marijuana-related art.¹⁰³ The USPTO issued the first marijuana plant patent in December 2016, Patent No. PP27,475.¹⁰⁴ In 2019, there were

⁹¹ See *id.*

⁹² See U.S. CONST. art I, § 8. The Patent Clause of the Constitution provided the constitutional authority for the Act. See *id.*

⁹³ 35 U.S.C. § 101 (2018).

⁹⁴ *Id.*

⁹⁵ See U.S. CONST. art I, § 8; 35 U.S.C. § 101 (2018).

⁹⁶ 447 U.S. 303 (1980).

⁹⁷ See *id.* at 310 (determining that the inventor’s new bacteria constituted patentable subject matter since it was his own work and not nature’s).

⁹⁸ See *id.*

⁹⁹ See 35 U.S.C. § 161 (2018).

¹⁰⁰ See *id.*

¹⁰¹ See Adli, *supra* note 31.

¹⁰² See generally ‘507 Patent, *supra* note 13; see Fraizer, *supra* note 14.

¹⁰³ See 35 U.S.C. § 101 (2018). Eligibility requires a “new and useful process, machine, manufacture, or composition of matter.” *Id.*

¹⁰⁴ See ‘475 Patent, *supra* note 14.

only three cannabis plant patents, but in 2020, the USPTO issued nine.¹⁰⁵ The owners of these cannabis and marijuana patents include private parties and even the U.S. government.¹⁰⁶ Cannabis-related patents were issued as early as September 2000, long before state legalization of marijuana.¹⁰⁷ The federal government's cannabis patent is a method patent for treating oxidation-associated diseases and inflammatory autoimmune diseases through the administration of CBD.¹⁰⁸ The patent summary states that some of the specific autoimmune diseases targeted include Parkinson's Disease, Alzheimer's, and HIV dementia.¹⁰⁹ Notably, the patent calls for "non-psychoactive" CBD in claim 2 and seven dependent claims.¹¹⁰ This patent was issued in 2003, prior to federal legalization of CBD,¹¹¹ and the acceptance of its claims appears to contradict the official federal policy of denying all medical utility of cannabis and marijuana under the CSA. Further, the federal government's ownership of an issued marijuana patent demonstrates that it ostensibly has (or had) an interest in enforcing its exclusive right.

F. Illegality Doctrine

When marijuana businesses inevitably bring federal lawsuits to enforce their patents, marijuana's illegal federal status makes it likely that the illegality doctrine will play a large role in deciding these cases.¹¹²

The illegality doctrine traces back to English law, when an English highwayman boldly attempted to enforce an oral agreement with his partner to split the proceeds of their robberies in the court of equity in *Everet v. Williams*.¹¹³ The English court refused to enforce the highwaymen's agreement because the profits were the fruits of their crimes.¹¹⁴ The illegality doctrine carried

¹⁰⁵ See Fraizer, *supra* note 14.

¹⁰⁶ See '507 Patent, *supra* note 13 (assignee is the United States as represented by the Department of Health and Human Services); U.S. Patent No. 11,154,579 (filed Nov. 5, 2019) (issued Oct. 26, 2021) (assignee is Jenny's Rose, LLC, a private company).

¹⁰⁷ See U.S. Patent No. 6,113,940 (filed Mar. 3, 1998) (issued Sept. 5, 2000). This patent was for a method of delivering cannabis to the bloodstream by applying a prepared bandage, strip, or covering to a person's skin. See *id.*

¹⁰⁸ See '507 Patent, *supra* note 13.

¹⁰⁹ See *id.*

¹¹⁰ *Id.* at col. 27–32.

¹¹¹ *Id.*

¹¹² See McNichol, *supra* note 12, at 52.

¹¹³ *The Highwayman's Case* (*Everet v. Williams*), 9 L. Q. REV. 197 (1893) (summarizing *Everet v. Williams*, the 1725 English case in which the illegality doctrine was first applied).

¹¹⁴ See *id.* at 198–99. Not only did the court not hear the suit but it turned the highwaymen in to the sheriff and fined their lawyers. See *id.* Apparently neither plaintiff nor defendant mended their ways as both would face the gallows only a few short years after the case. See *id.*

over into American law.¹¹⁵ The Supreme Court has articulated that “no court will lend its assistance in any way toward carrying out the terms of an illegal contract.”¹¹⁶ The Court stated that not only is an illegal contract unenforceable, but also that “any alleged rights discretely springing from such a contract” cannot be enforced.¹¹⁷ Currently, there is no definitive procedure for dealing with cannabis patent enforcement cases.¹¹⁸ Though the illegality doctrine originally applied to contract cases, it has been argued that the illegality doctrine could apply in marijuana patent infringement suits.¹¹⁹ A court very well could dismiss a marijuana patent infringement case due to the illegal nature of cannabis and marijuana under the CSA before ever reaching its merits.¹²⁰

The illegality doctrine relates to the potential limitation of marijuana patents under the “useful” requirement in § 101.¹²¹ This caveat arises from *Lowell v. Lewis*.¹²² In his opinion, Justice Story stated that “the law will not allow the plaintiff to recover, if the invention be of a mischievous or injurious tendency.”¹²³ He further stated, “The word ‘useful’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.”¹²⁴ These § 101 usefulness concerns were addressed by the Federal Circuit in *Juicy Whip, Inc. v. Orange Bang, Inc.*¹²⁵ The case involved a beverage dispenser that was designed to look deceptively like a competitor’s.¹²⁶ The Federal Circuit stated that an invention is useful if it is capable of providing an identifiable benefit.¹²⁷ Although the Federal Circuit recognized the principle of invalidating immoral

¹¹⁵ See McNichol, *supra* note 12, at 44–45.

¹¹⁶ McMullen v. Hoffman, 174 U.S. 639, 654 (1899).

¹¹⁷ *Id.*

¹¹⁸ See generally McNichol, *supra* note 12; Bernstein, *supra* note 17; Barritt et al., *supra* note 17; Pereira & Royka, *supra* note 17.

¹¹⁹ See McNichol, *supra* note 12, at 48; Bernstein, *supra* note 17.

¹²⁰ See McNichol, *supra* note 12, at 48; Bernstein, *supra* note 17; Barritt et al., *supra* note 17; Pereira & Royka, *supra* note 17.

¹²¹ See 35 U.S.C. § 101 (2018).

¹²² 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568). When he wrote this opinion, Justice Story was hearing cases in local circuit courts (circuit riding) even though he was a Supreme Court Justice. The Judicial Code of 1911 abolished the practice. See Joshua Glick, *On the Road: The Supreme Court and The History of Circuit Riding*, 24 CARDOZO L. REV. 1753, 1753–55 (2003).

¹²³ *Lowell*, 15 F. Cas. at 1019 (establishing the morality doctrine in patent law).

¹²⁴ *Id.*

¹²⁵ 185 F.3d 1364 (Fed. Cir. 1999) (demonstrating the way that immorality, mischievousness, and deception concerns are presently addressed in patent eligibility).

¹²⁶ See *id.* at 1365–66.

¹²⁷ See *id.* at 1366–67.

or illegal inventions, it stated that principle was no longer being applied.¹²⁸ The Federal Circuit's ruling signaled that the court would not invalidate patents for potential immoral or illegal applications because the patent utility requirement was never meant to replace the government's police powers.¹²⁹

G. Dope Patent Infringement

The first cannabis patent infringement complaint was filed in the United States District Court for Colorado in 2018 by United Cannabis Corporation ("UCANN") against Pure Hemp.¹³⁰ UCANN alleged Pure Hemp infringed its patent, which claimed numerous liquid formulations of cannabinoid extracts.¹³¹ UCANN asserted Pure Hemp infringed by producing products containing the cannabinoid formulations covered by its patent.¹³² Pure Hemp filed a motion for summary judgement alleging UCANN's patent was invalid because it covered natural phenomena.¹³³ The district court denied summary judgement and notably did not cite the illegality doctrine at all in its decision denying the motion.¹³⁴

This decision contradicts the conventional wisdom of many who thought the court would bring up the illegality doctrine *sua sponte* or dismiss for lack of standing because the alleged infringement violates the CSA.¹³⁵ Rather than introducing the illegality doctrine, the district court addressed the familiar

¹²⁸ See *id.* at 1366.

¹²⁹ See *id.* at 1368.

¹³⁰ See *Breaking News: First Cannabis Patent Lawsuit Filed*, HARRIS BRICKEN: CANNA LAW BLOG (Aug. 8, 2018), <https://harrisbricken.com/cannalawblog/breaking-news-first-cannabis-patent-lawsuit-filed/> [<https://perma.cc/636L-NH5C>].

¹³¹ See Complaint for Patent Infringement and Demand for Jury Trial, *supra* note 15, at 1–2; see also U.S. Patent No. 9,730,911 (filed Oct. 21, 2015) (issued Aug. 15, 2017) (UCANN's patent for CBD extracts from cannabis and methods for using the extract to treat various medical conditions).

¹³² See Complaint for Patent Infringement and Demand for Jury Trial, *supra* note 15, at 1, 5–6.

¹³³ See Defendant's Early Motion for Partial Summary Judgment, United Cannabis Corp. v. Pure Hemp Collective Inc., No. 1:18-cv-01922 (D. Colo. Nov. 29, 2018) (requesting judgement based on traditional patent law principles rather than on an illegality theory).

¹³⁴ See Order Denying Defendant's Early Motion for Partial Summary Judgment, *supra* note 15, at 1 (denying the motion based on traditional patent law principles and analysis rather than dismissing the case *sua sponte* on illegality doctrine grounds); cf. United Cannabis Corp. v. Pure Hemp Collective Inc., No. 1:18-cv-01922, 2021 WL 6063595 (D. Colo. Dec. 22, 2021).

¹³⁵ See McNichol, *supra* note 12, at 50–51; Bernstein, *supra* note 17, at 23 (predicting that marijuana patent infringement cases in federal court likely face dismissal due to illegality doctrine concerns).

patent law theme of eligibility.¹³⁶ The court inquired as to whether the patent was an abstract idea and whether it had an inventive concept to determine if it was ineligible under § 101 as natural phenomena.¹³⁷ The denial of summary judgement read like any other patent law decision.¹³⁸ The case went unresolved and was dismissed in early 2021 following UCANN's bankruptcy.¹³⁹ Ironically, UCANN's patent infringement case was not dismissed due to cannabis's illegal status, but rather because the USTP denied UCANN bankruptcy protection for that very reason, therefore causing the patent case to subsequently be dismissed.¹⁴⁰

In 2021, another cannabis patent infringement case was brought by Canopy Growth against GW Pharmaceuticals.¹⁴¹ Canopy Growth alleged infringement of its patent for a process for extracting CBD from a cannabis plant.¹⁴² Canopy Growth alleged that GW Pharmaceuticals infringed its patent by using the patented method to extract CBD.¹⁴³ GW Pharmaceuticals used the CBD extracted from the process in its product Epidiolex CBD, which had FDA approval to treat certain seizures.¹⁴⁴ GW Pharmaceuticals responded with a motion to dismiss for lack of jurisdiction and failure to state a claim on which relief could be granted.¹⁴⁵ GW Pharmaceuticals did not include an illegality doctrine argument in its motion to dismiss.¹⁴⁶ After a *Markman* hearing determined the patent claim construction at issue, the parties stipulated that Canopy Growth could not prevail on its infringement claim.¹⁴⁷ Canopy Growth subsequently notified the district court of its appeal to the Federal Circuit on the claim construction issue and final

¹³⁶ See Order Denying Defendant's Early Motion for Partial Summary Judgment, *supra* note 15, at 4–5; cf. *United Cannabis Corp.*, 2021 WL 6063595.

¹³⁷ See Order Denying Defendant's Early Motion for Partial Summary Judgment, *supra* note 15, at 11–13.

¹³⁸ See *id.* at 8–11.

¹³⁹ See Stipulation of Dismissal, *supra* note 15.

¹⁴⁰ See Leslie A. Pappas, *United Cannabis Bankruptcy Axed After DOJ Argued Pot Illegality*, BLOOMBERG LAW (Jan. 13, 2021, 3:24 PM), https://www.bloomberglaw.com/bloomberglawnews/bankruptcy-law/XACVVM0O000000?bna_news_filter=bankruptcy-law#jcite [<https://perma.cc/K64Q-786N>].

¹⁴¹ See Complaint for Patent Infringement, *supra* note 15.

¹⁴² See *id.* at 3.

¹⁴³ See *id.* at 5.

¹⁴⁴ See *id.*

¹⁴⁵ See Motion to Dismiss the Complaint, *Canopy Growth Corp. v. GW Pharms. PLC*, No. 6:20-cv-1180 (W.D. Tex. Mar. 5, 2021).

¹⁴⁶ See *id.*

¹⁴⁷ See Final Judgment, *supra* note 15, at 3–4.

judgement.¹⁴⁸ Because the only other cannabis patent case, *United Cannabis Corp. v. Pure Hemp Collective Inc.*,¹⁴⁹ was dismissed before it could be decided on the merits,¹⁵⁰ the *Canopy Growth* appeal will be a case of first impression for the Federal Circuit regarding cannabis and marijuana patents and their unique legal issues.

II. Analysis: Handling Marijuana Patent Infringement Cases

Although cannabis and marijuana policy has liberalized, marijuana still has the dubious status as a Schedule 1 narcotic under the CSA.¹⁵¹ The recent rapid succession of state marijuana legalization, coupled with the 2018 Farm Bill, which distinguishes legalized hemp from illegal marijuana based on THC levels, still leaves many legal questions unanswered.¹⁵² Most important for the purpose of this Note is the question of how federal courts will treat cannabis and marijuana patents in infringement cases.¹⁵³ Since the legal marijuana industry is in its early stages, there are few civil cases to rely on for precedent: only two cannabis and marijuana patent infringement suits have been brought thus far, *UCANN v. Pure Hemp* and *Canopy Growth v. GW Pharmaceuticals*.¹⁵⁴ Law review articles and law firm publications have speculated and opined on whether, and how, a cannabis infringement suit will be seen through to a verdict on the merits, in light of the illegality doctrine's potential impact on marijuana patent litigation.¹⁵⁵

The uncertainty surrounding if, and how, federal courts will adjudicate cannabis and marijuana patent infringement cases stems from the contrast between state and federal law.¹⁵⁶ This dichotomy leads to concerns that finding patent infringement in these cases may enable or condone violations of the CSA.¹⁵⁷ This concern is amplified when courts consider the remedies they

¹⁴⁸ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16.

¹⁴⁹ No. 1:18-cv-01922, 2021 WL 6063595 (D. Colo. Dec. 22, 2021).

¹⁵⁰ See *supra* notes 134–44 and accompanying text.

¹⁵¹ See 21 U.S.C. § 812 (2018).

¹⁵² See Agricultural Improvement Act of 2018, Pub. L. No. 115-334 132 Stat. 4908; Initiative 502, 2013 Wash. Laws ch. 3; COLO. CONST. Art. XVIII, § 16.

¹⁵³ See Bernstein, *supra* note 17; McNichol, *supra* note 12; Barritt et al., *supra* note 17; Pereira & Royka, *supra* note 17.

¹⁵⁴ See Complaint for Patent Infringement and Demand for Jury Trial, *supra* note 15; Complaint for Patent Infringement, *supra* note 15.

¹⁵⁵ See Bernstein, *supra* note 17; McNichol, *supra* note 12; Barritt et al., *supra* note 17; Pereira & Royka, *supra* note 17.

¹⁵⁶ See 2013 Wash. Sess. Laws 28; COLO. CONST. art. XVIII, § 16; 21 U.S.C. § 812 (2018).

¹⁵⁷ See McNichol, *supra* note 12, at 48–49.

would need to apply after a finding of infringement.¹⁵⁸ The Federal Circuit will soon get a chance to provide clarity.¹⁵⁹ Canopy Growth recently appealed to the Federal Circuit disputing the district court's claim construction and final judgement in *Canopy Growth v. GW Pharmaceuticals*.¹⁶⁰ The Federal Circuit's *Juicy Whip* decision hints that it disfavors using the illegality doctrine to invalidate patents.¹⁶¹ While other federal courts have demonstrated their competence in the adjudication of the few civil cases they have decided involving marijuana,¹⁶² clarity is needed in this area as parties in infringement suits likely have no incentive to challenge patents on CSA grounds and because carte blanche dismissals of these infringement suits could create absurd results.

A. Injunctive or Monetary Relief

The relief a patentee seeks in cannabis and marijuana infringement suits could influence whether a court decides to hear or dismiss the case. The court may either grant the equitable remedy of an injunction, award a legal remedy of monetary damages, or both if it finds patent infringement.¹⁶³ Some courts may be wary of awarding monetary damages after finding infringement of a cannabis or marijuana patent, adopting a viewpoint similar to that of the USTP in bankruptcy cases or the English court in *Everet v. Williams* finding that damages would reward illegal activity.¹⁶⁴ For these courts, awarding monetary damages for marijuana patent infringement would be similar to enforcing the highwaymen's agreement to split the ill-gotten gains of burglaries in *Everet v. Williams*.¹⁶⁵ Courts may likely view the awarded damages as essentially an endorsement of violations of the CSA.¹⁶⁶

For policy reasons, injunctive relief may be a more palatable resolution to a court hesitant to award monetary damages to a cannabis or marijuana patent owner.¹⁶⁷ The Supreme Court ruled that granting injunctions is at the equitable discretion of district courts after a finding of infringement.¹⁶⁸

¹⁵⁸ See 35 U.S.C. §§ 283–284 (2018).

¹⁵⁹ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16.

¹⁶⁰ See *id.*

¹⁶¹ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

¹⁶² See *Toigo v. Dep't of Health & Senior Servs. et al.*, 549 F. Supp. 3d 985 (W.D. Mo. 2021); *Green Earth Wellness Ctr., LLC v. Atain Specialty Ins. Co.*, 163 F. Supp. 3d 821, 832 (D. Colo. 2016).

¹⁶³ See 35 U.S.C. §§ 283–284.

¹⁶⁴ See *McNichol*, *supra* note 12, at 48–49; *White & Sheahan*, *supra* note 68, at 34; *The Highwayman's Case*, *supra* note 113, at 198–99.

¹⁶⁵ See *The Highwayman's Case*, *supra* note 113, at 198–99.

¹⁶⁶ See *McNichol*, *supra* note 12, at 48–49; *White & Sheahan*, *supra* note 68.

¹⁶⁷ See *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006).

¹⁶⁸ See *id.* at 394.

Courts may view monetary damages as improperly awarding patent owners who are violating the CSA; however, they may consider it good public policy to instead grant an injunction preventing the infringer from violating the CSA.¹⁶⁹ This course of action would not be unreasonable. After a finding of infringement, 35 U.S.C. § 284¹⁷⁰ mandates awarding damages that are no less than a “reasonable royalty” and allows courts to set damages if the jury does not.¹⁷¹ Courts could justify their denial of monetary damages because there is no reasonable royalty for breaking the law.¹⁷² By granting injunctions, courts can prevent patent holders from profiting from the perceived violations of the CSA while also fulfilling the public interest in stopping infringers from violating the CSA further.

Concerns about using the judiciary to reward illegal behavior could lead federal courts to dismiss marijuana patent infringement cases without reaching the merits.¹⁷³ The USTP’s policy and success at dismissing marijuana industry bankruptcy cases demonstrates that federal district courts can dismiss cannabis or marijuana patent infringement suits due to CSA considerations.¹⁷⁴ The USTP analyzes not just bankruptcy law, but numerous other federal laws as well, when considering if the debtor can be granted relief.¹⁷⁵ The USTP has had success in dismissing these bankruptcies, as evidenced by UCANN’s bankruptcy case.¹⁷⁶ The USTP’s policy demonstrates that a party can request enforcement of the illegality doctrine and that courts can raise this issue *sua sponte* if they wish.¹⁷⁷ The two cannabis patent infringement cases that have appeared before federal district courts were not dismissed in such a manner; however, until the Federal Circuit provides definitive guidance, other district courts could dismiss a case under the illegality doctrine at their discretion.¹⁷⁸ Federal Circuit guidance here could provide much-needed clarity for future cases.

¹⁶⁹ See *id.* at 391.

¹⁷⁰ 35 U.S.C. § 284 (2018).

¹⁷¹ *Id.*

¹⁷² See McNichol, *supra* note 12, at 48–49.

¹⁷³ See *id.*

¹⁷⁴ See Pappas, *supra* note 140.

¹⁷⁵ See White & Sheahan, *supra* note 68.

¹⁷⁶ See Pappas, *supra* note 140.

¹⁷⁷ See McNichol, *supra* note 12, at 50–51; White & Sheahan, *supra* note 68.

¹⁷⁸ See generally Stipulation of Dismissal, *supra* note 15; see Final Judgment, *supra* note 15, at 4.

B. Cost of Inaction

Without a clear resolution as to how marijuana and cannabis patent enforcement can proceed, members of the marijuana industry will not know if they will be able to protect their marijuana-related intellectual property.¹⁷⁹ This could lead to collective hesitation in investing in R&D or may spur alternate strategies that attempt to protect intellectual property.¹⁸⁰ If federal courts turn a blind eye to patent infringement when it occurs in cannabis or cannabis-related inventions, it would further incentivize breaking of patent and narcotics law by tacitly rewarding—or at least not punishing—this infringement. Refusal to enforce these patents could be used as precedent to weaken or disregard patent rights. If courts have the discretion to ignore their duty to protect cannabis patents, courts could also attempt to use public policy to justify their failure to protect patents in various disfavored industries.¹⁸¹ For instance, oil and drilling industry patents could be disregarded by courts that decide the public policy concerns of environmental and climate change trump the benefit gained by enforcing patent rights. Resolution on the issue of enforcing marijuana and cannabis patents is also needed because it is only a matter of time until many more marijuana and cannabis patent infringement cases find themselves before the courts.

C. The Federal Circuit Can Provide Clarity

Canopy Growth's notice of appeal on the final judgement of noninfringement and claim construction in *Canopy Growth v. GW Pharmaceuticals* will give the Federal Circuit its first chance to hear a cannabis patent infringement case.¹⁸² The Federal Circuit could also hear another subsequent marijuana patent infringement appeal if a new case is brought and dismissed *sua sponte* due to the illegality doctrine.¹⁸³ An appeal after such a dismissal would require the Federal Circuit to decide how district courts should treat cannabis and marijuana patent infringement cases in light of the CSA.¹⁸⁴ The Federal Circuit has the opportunity to provide guidance on how the illegality doctrine should affect marijuana and cannabis patent infringement cases, if at all, when it hears the *Canopy Growth* appeal.¹⁸⁵ While the Federal Circuit has not heard a

¹⁷⁹ See McNichol, *supra* note 12, at 28.

¹⁸⁰ See *id.*; see also Bernstein, *supra* note 17.

¹⁸¹ See, e.g., eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 394 (2006).

¹⁸² See *supra* notes 154–60 and accompanying text.

¹⁸³ See McNichol, *supra* note 12, at 50–51.

¹⁸⁴ See *id.*

¹⁸⁵ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16.

case like this yet, it has given clues on how it may approach such a dilemma in its previous ruling in *Juicy Whip v. Orange Bang*.¹⁸⁶

1. *Juicy Whip's Legacy*

The Federal Circuit has heard other patent cases involving whether the immorality or illegality of an invention can be the basis of invalidating a patent.¹⁸⁷ In the seminal case of *Juicy Whip v. Orange Bang*, the Federal Circuit observed there was a trend departing away from Justice Story's principle of invalidation for immorality or illegality.¹⁸⁸ Following this trend, the Federal Circuit refused to invalidate a patent that was designed to deceptively mimic a competitor's beverage dispenser.¹⁸⁹ In furtherance of the Supreme Court's stance that "Congress never intended that the patent laws should displace the police powers of the States,"¹⁹⁰ the Federal Circuit clarified that "Congress is free to declare particular types of inventions unpatentable for a variety of reasons."¹⁹¹ The *Juicy Whip* opinion articulates the Federal Circuit's position that it will not step outside of patent law to invalidate patents on behalf of other federal agencies even if the patent could enable immoral or illegal activity.¹⁹² This suggests the Federal Circuit would likely not strike down a marijuana or cannabis patent on utility grounds as long as the invention has some use, regardless of the underlying CSA considerations.¹⁹³ The *Juicy Whip* opinion suggests the Federal Circuit would act this way because it is hesitant to assume the role and responsibilities of other agencies' police powers.¹⁹⁴ The Federal Circuit pointed out that the Federal Trade Commission ("FTC") and FDA have the role of protecting the public regarding food sales.¹⁹⁵ Similarly, the DEA, FDA, and DOJ are responsible for protecting the public by carrying out drug and narcotics policies.¹⁹⁶ The *Juicy Whip* precedent suggests the Federal Circuit would not step into a federal agency's role of enforcing the CSA and would maintain its proper role of adjudicating a marijuana patent infringement case, allowing it to move forward on the merits. It seems even more likely that the Federal Circuit would rely on this reasoning when the DOJ itself often does not enforce the CSA against legal state-level marijuana

¹⁸⁶ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1364 (Fed. Cir. 1999).

¹⁸⁷ See *id.* at 1366.

¹⁸⁸ See *id.* at 1366–67.

¹⁸⁹ See *id.* at 1367–68.

¹⁹⁰ *Webber v. Virginia*, 103 U.S. 344, 347–48 (1880).

¹⁹¹ *Juicy Whip*, 185 F.3d at 1368.

¹⁹² See *id.*

¹⁹³ See *id.*

¹⁹⁴ See *id.*

¹⁹⁵ See *id.*

¹⁹⁶ See generally 21 U.S.C. § 812; DRUG FACT SHEET, *supra* note 9.

Neither party in a cannabis or marijuana patent infringement suit benefits from challenging the patent or their opposing party based on the illegality doctrine. This was evidenced in both the cannabis patent infringement suits brought in federal court so far, as no party raised the illegality doctrine in their motions for summary judgement.¹⁹⁸ The defendants in both cases were established in the cannabis industry and had an interest in ensuring the value of intellectual property in the marijuana industry.¹⁹⁹ GW Pharmaceuticals, the defendant in the infringement suit brought by Canopy Growth, held numerous cannabis and marijuana related patents.²⁰⁰ If GW Pharmaceuticals had succeeded on its motion to dismiss citing the illegality defense, GW Pharmaceuticals would need to overcome that same defense when asserting its own patent rights against infringement. A successful infringement defense based on marijuana's illegal status under the CSA will likely prove to be a pyrrhic one if that defendant also owns cannabis and marijuana patents. Victory on those grounds would pave the way for any party infringing cannabis and marijuana patents to dismiss the infringement case without reaching the merits.

Courts dismissing cannabis and marijuana patent infringement cases *sua sponte* because of the illegality doctrine would lead to absurd results. Invoking the illegality doctrine to dismiss infringement cases would not stop marijuana or cannabis-related activity, but rather allow the illegal activity to continue. After a court reaches a finding of patent infringement under § 271, §§ 283 and 284 define the potential remedies as either injunctive relief, monetary

²⁰⁰ See RESULTS OF SEARCH IN USPTO PATENT DATABASE FOR GW RESEARCH LIMITED, U.S. PAT. & TRADEMARK OFF., <https://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=GW+Research+Limited&FIELD1=ASN&co1=AND&TERM2=&FIELD2=&d=PTXT> [https://perma.cc/C3DT-YNE8] (last visited Sept. 19, 2022).

damages, or both.²⁰¹ Injunctive relief would prevent both further infringement and continued violations of the CSA.²⁰² Dismissing a cannabis patent infringement case under the illegality doctrine would prevent the case from proceeding, removing the ability for courts to find infringement and preventing them from employing their most useful tool of equitable relief to enjoin further illegal activity.²⁰³ Eliminating the possibility of granting an injunction against a marijuana patent infringer who violates the CSA simply because the patentee may be doing the same is an absurd result if the federal government wants to minimize CSA violations or cannabis use and distribution.

F. Further Absurdity

The absurdity discussed above is especially highlighted in the case of non-practicing entities. Many players in the patent realm are non-practicing entities, meaning they hold patents but do not sell or produce products.²⁰⁴ These non-practicing entities are often universities or individual investors who use their patents for licensing or further research.²⁰⁵ Dismissing any case involving marijuana patentees would hurt non-practicing entities including the federal government, individual marijuana patent owners, and leading cannabis researchers.²⁰⁶ If the Federal Circuit sets a precedent for blanket dismissals of cannabis and marijuana patents, it would effectively strip these patent owners of their exclusive right by making their patents unenforceable.²⁰⁷ This, in turn, would remove most of the profit incentive for continued cannabis research, even in legitimate fields like medicine, since new technologies would not get the benefit of true patent protection.²⁰⁸ This would unfairly hurt non-practicing entity patent owners who would subsequently be denied remedies for patent infringement even though their use of the technology does not violate the CSA.²⁰⁹ At the same time, blanket dismissals based on potential illegal activity would essentially reward infringers who not only infringe said marijuana and cannabis patents, but also continue violating the CSA unabated.

²⁰¹ See 35 U.S.C. §§ 271, 283–284 (2018).

²⁰² See 35 U.S.C. §§ 271, 283–284.

²⁰³ See 35 U.S.C. § 283 (2018).

²⁰⁴ See *Non-Practicing Entity (NPE)*, THOMSON REUTERS PRAC. L. GLOSSARY, <https://us.practicallaw.thomsonreuters.com/4-513-0928> [<https://perma.cc/4YUC-JTSS>] (last visited Sept. 19, 2022).

²⁰⁵ See Cerwinski et al., *supra* note 21.

²⁰⁶ See ‘507 Patent, *supra* note 13; NATIONAL INSTITUTES OF HEALTH, *supra* note 56.

²⁰⁷ See Cerwinski et al., *supra* note 21; McNichol, *supra* note 12, at 51.

²⁰⁸ See Cerwinski et al., *supra* note 21; McNichol, *supra* note 12, at 51.

²⁰⁹ See Cerwinski et al., *supra* note 21.

The view that holding a cannabis or marijuana patent grants a right to take part in illegal activity is inaccurate and stems from the misguided viewpoint that patents are a grant to hold a monopoly.²¹⁰ In actuality, the patent grant is an exclusive right: it allows the owner to exclude others from making use of their patent for a limited period of time.²¹¹ Unlike a monopolist, the patentee gains their exclusive rights by providing a public service by disclosing their patent to the public, furthering public knowledge and advancements.²¹² If the federal government's goal is reducing cannabis and marijuana use and abuse, enforcing cannabis and marijuana patents would aid that goal. Injunctions against marijuana and cannabis patent infringers would prevent anyone other than patentees and licensees from practicing the cannabis and marijuana patents at issue.²¹³ An injunction would keep infringing entities from taking advantage of these patents and prevent subsequent violations of the CSA.²¹⁴ Monetary damages would also provide a deterrent effect on potential infringers by incentivizing them to refrain from infringing on marijuana patents and putting a cost on infringing activity that violates the CSA.²¹⁵

G. Marijuana Patent Cases in Federal Court

The two cannabis patent infringement suits brought before U.S. district courts to date show that federal courts are capable of properly applying patent law in adjudicating cannabis patent infringement suits.²¹⁶ In both *UCANN* and *Canopy Growth*, the courts heard and decided motions on the merits, including denying defendants' motions to dismiss, and declined to *sua sponte* bring up marijuana's legal status.²¹⁷ In *UCANN*, Pure Hemp made § 101 arguments in its motion to dismiss by arguing the patent for CBD covered natural phenomena.²¹⁸ The court analyzed Pure Hemp's § 101 patentability argument by applying the Supreme Court's *Alice* test for § 101 patentability.²¹⁹ While *UCANN*'s suit was ultimately dismissed due to *UCANN*'s bankruptcy,

²¹⁰ See *id.*

²¹¹ See U.S. CONST. art I, § 8.

²¹² See *id.*; 35 U.S.C. § 112 (2018).

²¹³ See 35 U.S.C. § 283 (2018).

²¹⁴ See *id.*

²¹⁵ See 35 U.S.C. § 284 (2018).

²¹⁶ See Complaint for Patent Infringement and Demand for Jury Trial, *supra* note 15; Complaint for Patent Infringement, *supra* note 15.

²¹⁷ See Motion to Dismiss the Complaint, *supra* note 145; Defendant's Early Motion for Partial Summary Judgment, *supra* note 133; Order Denying Defendant's Early Motion for Partial Summary Judgment, *supra* note 15; Final Judgment, *supra* note 15.

²¹⁸ See Defendant's Early Motion for Partial Summary Judgment, *supra* note 133, at 4–5.

²¹⁹ See Order Denying Defendant's Early Motion for Partial Summary Judgment, *supra* note 15, at 5–10.

the district court's analysis suggests the case could have proceeded and been decided on § 101 patentability grounds.²²⁰ In Canopy Growth's infringement suit against GW Pharmaceuticals, GW Pharmaceuticals argued the court lacked personal jurisdiction in its motion to dismiss.²²¹ The later *Markman* claim construction order would prove decisive and result in the district court's final judgement.²²² These cases show that district courts are more than capable of applying patent law principles in resolving cannabis and marijuana patent infringement cases, but there is still no established uniform standard for handling such cases throughout the district courts.²²³

H. Consistency with Marijuana Civil Cases in Federal Court

The two federal district courts that heard cannabis patent infringement cases to date handled those cases in a manner consistent with the few other prior federal district court non-patent civil cases related to marijuana.²²⁴ In one of those non-patent civil cases, *Green Earth Wellness*, the District of Colorado ruled on the merits.²²⁵ This case was a diversity action, and while the court noted marijuana's status under the CSA, the decision relied on principles of state contract law.²²⁶ In *Toigo*, which was also about the medical marijuana industry, the District Court for the Western District of Missouri²²⁷ granted a preliminary injunction and final ruling on the merits while also making note of recreational marijuana's illegal status in its opinion.²²⁸ In doing so, the court ruled that the constitutional prohibition of states unduly burdening interstate commerce still applied to the marijuana industry despite the CSA.²²⁹

²²⁰ See *id.* at 12–13; Stipulation of Dismissal, *supra* note 15.

²²¹ See generally Motion to Dismiss the Complaint, *supra* note 145. As a defendant, GW Pharmaceuticals declined to assert an illegality doctrine defense for a patent that has applications that can be illegal. See *id.* Rather, GW Pharmaceuticals argued for dismissal based on lack of personal jurisdiction and for Canopy Growth's failure to state a claim for infringement. See *id.* at 4–6.

²²² See Final Judgment at 4, *supra* note 15.

²²³ See generally Stipulation for Dismissal, *supra* note 15; Final Judgment, *supra* note 15.

²²⁴ See *Green Earth Wellness Ctr., LLC v. Atain Specialty Ins. Co.*, 163 F. Supp. 3d 821, 832 (D. Colo. 2016); *Toigo v. Dep't of Health and Senior Servs.*, 549 F. Supp. 3d 985, 988 (W.D. Mo. 2021). See generally Stipulation of Dismissal, *supra* note 15; Final Judgment, *supra* note 15.

²²⁵ See *Green Earth Wellness*, 163 F. Supp. 3d at 834.

²²⁶ See *id.*

²²⁷ See *Toigo*, 549 F. Supp. 3d at 990–91.

²²⁸ See *id.* at 991.

²²⁹ See *id.* at 990–91.

All the cannabis and marijuana-related federal cases, whether patent or civil, were decided at the district court level.²³⁰ Since only a small number of district courts have rendered decisions in cannabis or marijuana-related civil or patent cases, there is no precedent or universal standard for district courts to follow. The *Canopy Growth* appeal will be a case of first impression for the Federal Circuit, and the Federal Circuit could remedy the lack of precedent surrounding cannabis and marijuana patent infringement suits by ruling such cases should be heard and decided on the merits. While the Federal Circuit could decide to dismiss the case due to marijuana's status under the CSA, its *Juicy Whip* precedent suggests the case should be heard and decided on the merits.²³¹ Alternatively, the Federal Circuit could still decide that the illegality doctrine and public policy considerations of marijuana's status under the CSA require departure from *Juicy Whip*'s reasoning and dismissing these cases.²³²

III. Solution: Enforce Marijuana Patents Against Infringement

The best solution for handling cannabis and marijuana patent infringement suits is for courts to hear and decide cases as they would infringement cases for any other patent subject art. Critics may argue that courts should dismiss these cases if it is determined that the cannabis or marijuana patent results in a CSA violation. Previous analysis suggests, however, that courts could adopt an approach similar to the USTP's and dismiss all cannabis and marijuana patent infringement suits for leading to violations of the CSA pursuant to the illegality doctrine.²³³

If federal courts adopt the first approach, as this Note advocates they should, they will promote predictability and stability regarding these patent suits; conversely, adopting the latter approach will perpetuate continued confusion, unpredictability, and absurd results.²³⁴ The *Canopy Growth* appeal is a chance for the Federal Circuit to provide clarity with a standard practice of hearing and deciding cannabis and marijuana patent infringement cases.²³⁵ The Federal Circuit should build on its *Juicy Whip* legacy by affirmatively stating that marijuana's federal illegal status under the CSA should not prevent cannabis patent infringement cases from being heard and decided on the merits. Such guidance from the Federal Circuit would create consistency

²³⁰ See Stipulation for Dismissal, *supra* note 15; Final Judgment, *supra* note 15; *Toigo*, 549 F. Supp. 3d 985; *Green Earth Wellness*, 163 F. Supp. 3d 821.

²³¹ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367–68 (Fed. Cir. 1999).

²³² See *id.* at 1366–68.

²³³ See McNichol, *supra* note 12, at 50–52; White & Sheahan, *supra* note 68, at 34.

²³⁴ See Adli, *supra* note 31.

²³⁵ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16.

when hearing cannabis and marijuana patent infringement cases and align with how federal courts have treated non-patent civil cases involving the cannabis and marijuana industry.²³⁶

A. Decide Cannabis and Marijuana Infringement Cases on the Merits

Both of the cannabis patent infringement cases that appeared in federal courts were handled and disposed of in the manner of typical patent infringement cases.²³⁷ The district courts did not take issue with the cannabis subject matter nor consider potential CSA issues in suit.²³⁸ Although *Canopy Growth* did not proceed all the way to a jury trial on the merits, the final judgement stemming from the court's Claim Construction Order reads like any other normal patent case adjudication.²³⁹ Other than the cannabis subject matter being new to federal patent cases, *Canopy Growth* seems like a typical patent dispute all the way through *Canopy Growth's* notice of its appeal and filings with the Federal Circuit.²⁴⁰

The dankest outcome from this appeal would be for the Federal Circuit to hear and decide the case on the merits. The Federal Circuit deciding that marijuana's legal status is not a bar to hearing and deciding marijuana and cannabis patent infringement cases would create stability and predictability in the marijuana and cannabis patent sphere.²⁴¹ It would put cannabis and marijuana patent owners on notice that they can pursue patent infringement claims without fearing the unpredictability of a *sua sponte* dismissal.²⁴² Another likely benefit of the Federal Circuit hearing a cannabis or marijuana patent case on the merits is that it would clear up the confusion and uncertainty of whether these patents are enforceable.²⁴³ Such clarification would

²³⁶ See *Toigo v. Dep't of Health and Senior Servs.*, 549 F. Supp. 3d 985 (W.D. Mo. 2021); *Green Earth Wellness Ctr., LLC v. Atain Specialty Ins. Co.*, 163 F. Supp. 3d 821 (D. Colo. 2016).

²³⁷ See generally Stipulation for Dismissal, *supra* note 15; Final Judgment, *supra* note 15.

²³⁸ See Final Judgment, *supra* note 15, at 4.

²³⁹ See Final Judgment, *supra* note 15, at 4.

²⁴⁰ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16; Appellant Canopy Growth Corp.'s Principal Brief, *Canopy Growth Corp. v. GW Pharms. Ltd.*, No. 22-1603 (Fed. Cir. Jun. 21, 2022); Response Brief of Defendants-Appellees, *Canopy Growth Corp.*, No. 22-1603 (Aug. 15, 2022).

²⁴¹ A Federal Circuit decision on this point could possibly be heard by the Supreme Court but is unlikely due to its low acceptance rate. See *Success Rate of a Petition for Writ of Certiorari to the Supreme Court*, SUPREME COURT PRESS, https://supremecourtpress.com/chance_of_success.html [<https://perma.cc/S7CY-JSVQ>] (last visited Nov. 5, 2022).

²⁴² See McNichol, *supra* note 12, at 50–51.

²⁴³ See Adli, *supra* note 31.

deter potential infringers and give patent owners a predictable framework in which they may protect their intellectual property.²⁴⁴

The Federal Circuit ensuring that marijuana and cannabis patent infringement is treated like other subject matter is the most logical and consistent position based on the USPTO's practices and patent law.²⁴⁵ The USPTO has issued marijuana plant and utility patents for years.²⁴⁶ Patent infringement under § 271 is not dependent on whether the underlying actions that infringe the patent are legal or illegal under other federal laws.²⁴⁷ Cannabis and marijuana patents should not be entitled to a new legal framework because the existing patent law framework involving validity, obviousness, novelty, and infringement is perfectly adequate to handle these patents.²⁴⁸ This legal framework does not distinguish between whether a patented invention could be used for legal or illegal purposes.²⁴⁹ Similarly, the availability of injunctive relief and other legal remedies in patent infringement cases is not dependent on the patent's subject matter.²⁵⁰ This solution would promote further consistency in the patent law framework.

A Federal Circuit ruling that cannabis and marijuana patent infringement suits should go forward on the merits will expand its statement in *Juicy Whip* and re-emphasize that patent law is not a replacement for the government's police powers.²⁵¹ This would put all interested parties in cannabis and marijuana patent infringement litigation on notice that federal district courts will only resolve the case before them. This would be a useful reminder that if the DOJ, DEA, and their political leadership want to prosecute marijuana violations of the CSA, they should bring enforcement actions themselves.²⁵² This notice would make patent owners and potential infringers base their actions on the knowledge that a cannabis patent infringement suit will not turn into a CSA enforcement action but will instead proceed in accordance with traditional patent law principles.²⁵³

²⁴⁴ See *id.*

²⁴⁵ See '475 Patent, *supra* note 14; '507 Patent, *supra* note 13; 35 U.S.C. § 271.

²⁴⁶ See '507 Patent, *supra* note 13.

²⁴⁷ See 35 U.S.C. § 271 (2018).

²⁴⁸ See 35 U.S.C. §§ 102–103, 271 (2018).

²⁴⁹ See 35 U.S.C. §§ 101–103, 271 (2018).

²⁵⁰ See 35 U.S.C. §§ 283–284.

²⁵¹ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999).

²⁵² See *Cole*, *supra* note 27, at 217–19.

²⁵³ See *McNichol*, *supra* note 12, at 50–51. See generally 35 U.S.C. §§ 101–103, 271 (2018).

B. *Sua Sponte* Dismissals Promote Uncertainty

Some critics believe an alternative solution for the courts would be to use the illegality doctrine to dismiss these infringement cases if the court finds the cannabis or marijuana patent at issue enables CSA or state law violations. While this approach may seem reasonable, its proponents are wrong because it is an unworkable solution. *Sua sponte* illegality doctrine dismissals would create unpredictability because of the nature of the cannabis plant, the arbitrary distinction between hemp and marijuana, and the nature of cannabis and marijuana patents.²⁵⁴ The cannabis plant includes both THC and CBD, but the 2018 Farm Bill distinguished legal hemp from illegal marijuana based solely on the percentage levels of THC rather than distinctions in the cannabis plant family.²⁵⁵ Since cannabis and marijuana patents often relate to both THC and CBD,²⁵⁶ methods used to extract CBD in compliance with state or federal laws can also be used to extract THC and violate the CSA. Analyzing whether the patent could be used to violate the law would add a burdensome test that is outside the scope of patentability under existing patent law.²⁵⁷ Under this approach, a court would be required to analyze the patent's applicable cannabis plant's THC levels before deciding if the case could even proceed. This would add unpredictability because certain hemp CBD applications of the patent would be legal while marijuana CBD and THC applications would be illegal.²⁵⁸ This extra layer of analysis and scrutiny would also contradict the Federal Circuit's approach to morality and illegality in *Juicy Whip*.²⁵⁹ Thus, a policy of blanket dismissals by courts citing the illegality doctrine is not a viable solution to handling and disposing of marijuana patent infringement suits.

C. Categorical Dismissals Would Create Absurd Results

Critics of allowing cannabis and marijuana patent infringement suits to go forward likely would prefer that courts dismiss these cases *sua sponte* as against public policy if a party does not request dismissal on illegality doctrine grounds.²⁶⁰ However, this contradicts the precedent and history of federal courts as they have successfully heard and decided patent and civil

²⁵⁴ See DiLonardo, *supra* note 32, at 1, 2, 4.

²⁵⁵ See *id.* at 1, 3; 7 U.S.C. § 1639o.

²⁵⁶ See, e.g., '507 Patent, *supra* note 13 (a method patent for treating certain diseases through the administration of CBD); '911 Patent, *supra* note 131 (patent for certain CBD extracts and for the method of extraction from both hemp and marijuana plants).

²⁵⁷ See 35 U.S.C. §§ 101–103 (2018).

²⁵⁸ See *id.*

²⁵⁹ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

²⁶⁰ See McNichol, *supra* note 12, at 50–51.

cases related to the cannabis and marijuana industry.²⁶¹ More importantly, categorical dismissals could lead to courts being unable to provide injunctive relief to remedy and prevent further patent infringement that violates the CSA. Courts taking this action would not want to enforce patents whose patentees could practice their patents and violate the CSA regardless of whether the patentee was actually practicing the patent in a manner that violates the CSA. This would be extremely absurd in cases where the patent owner is a non-practicing entity and cannot get relief, but the infringers who violate the CSA are not held accountable. This approach makes no sense if the goal is to cut down on potential CSA violations.

D. Federal Court Consistency

Federal courts have demonstrated that they are more than capable of hearing and resolving both civil and patent cases involving cannabis and marijuana on the merits.²⁶² Unfortunately, these cases hold little precedential value because they were disposed of in district courts and the other districts have no obligation to follow suit.²⁶³ The Federal Circuit has the unique opportunity to provide a nationwide standard that promotes consistency in approaching and adjudicating patent infringement cases involving cannabis and marijuana.²⁶⁴ A Federal Circuit ruling that marijuana and cannabis patent infringement cases shall be heard on the merits would apply that standard to all federal districts.²⁶⁵ While a Federal Circuit ruling would not bind non-patent civil cases, it would provide a potentially useful and analogous appellate opinion that could aid district courts when handling their first cannabis and marijuana non-patent civil cases.

In issuing an opinion, the Federal Circuit could even echo prior civil cases and note marijuana's status under the CSA while finding that federal courts should still hear and decide cannabis and marijuana patent infringement cases on the merits.²⁶⁶ For example, in *Toigo*, the Western District of Missouri refrained from a *sua sponte* dismissal, which would have prevented Mr. Toigo's potentially expanded role in Missouri's medical marijuana business.²⁶⁷ Rather, the court issued an injunction based on the merits of the arguments Mr.

²⁶¹ See *Toigo v. Dep't of Health and Senior Servs.*, 549 F. Supp. 3d 985, 988 (W.D. Mo. 2021); *Green Earth Wellness Ctr., LLC v. Atain Specialty Ins. Co.*, 163 F. Supp. 3d 821, 837 (D. Colo. 2016); Final Judgment at 4, *supra* note 15.

²⁶² See *Toigo*, 549 F. Supp. 3d at 988; *Green Earth Wellness*, 163 F. Supp. 3d at 837.

²⁶³ See *Toigo*, 549 F. Supp. 3d at 988; *Green Earth Wellness*, 163 F. Supp. 3d at 837.

²⁶⁴ See Plaintiff Canopy Growth Corporation's Notice of Appeal, *supra* note 16, at 1.

²⁶⁵ See *Just the Facts*, *supra* note 24.

²⁶⁶ See, e.g., *Toigo*, 549 F. Supp. 3d at 988; *Green Earth Wellness*, 163 F. Supp. 3d at 835.

²⁶⁷ See *Toigo*, 549 F. Supp. 3d at 988.

Toigo made about the Dormant Commerce Clause.²⁶⁸ Similarly, the District of Colorado refused to dismiss the case when the defendant raised the issue of the plaintiff's dispensary business in *Green Earth Wellness*.²⁶⁹ Instead of dismissing the case on public policy grounds, the court decided the case on state law contract grounds, since the defendant broke contractual obligations.²⁷⁰ The court reasoned that it was purely adjudicating contract law, but also seemed to imply that it did not want to upend contract predictability when Atain knew it was insuring the Green Earth Wellness's medical marijuana inventory.²⁷¹ The refusal of the *Green Earth Wellness* court to step outside the bounds of the insurance contract case to enforce other federal law is a similar approach to the Federal Circuit's *Juicy Whip* reasoning.²⁷² A Federal Circuit ruling that requires a merits-based approach to cannabis and marijuana patent infringement cases will help maintain a predictable and stable set of rules for the patent legal landscape.

Conclusion

Marijuana state-level policy continues to trend in the direction of decriminalization and legalization. The cannabis and marijuana industries are rapidly expanding, therefore, the need for a predictable legal framework in the enforcement of cannabis and marijuana patents is necessary. Cannabis and marijuana patentees, like any other patentees, should be able to benefit from the exclusive right their patent provides when said patents are issued by the USPTO. The Federal Circuit will soon have the chance to provide clarity in cannabis and marijuana patent infringement suits when it hears the *Canopy Growth* appeal. Federal Circuit guidance that cannabis and marijuana patent infringement suits should be heard and decided on the merits is the best way to promote stability and predictability in patent law. Such guidance would uphold patent rights, stop blunt infringers, and provide fair outcomes for patent owners as the marijuana industry continues rolling into the future.

²⁶⁸ See *id.* at 996. The Dormant Commerce Clause prevents states from placing an undue burden on interstate commerce. See *id.* at 990.

²⁶⁹ See *Green Earth Wellness*, 163 F. Supp. 3d at 835.

²⁷⁰ See *id.* at 834.

²⁷¹ See *id.* at 833–34.

²⁷² See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999); *Green Earth Wellness*, 163 F. Supp. 3d at 821.

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